



Australian Government

**Department of Health,
Disability and Ageing**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 July 2026

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 July 2026 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$9.24
	Dangerous drug fee	\$5.73
	Extemporaneously-prepared	\$11.28
	Allowable additional patient charge*	\$2.79
Additional Fees (for safety net prices):	Ready-prepared	\$1.54
	Extemporaneously-prepared	\$1.99
Patient Co-payments:	General	\$25.00
	Concessional	\$7.70
Safety Net Thresholds:	General	\$1748.20
	Concessional	\$277.20
Safety Net Card Issue Fee:		\$12.78

* 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 July 2026. The Schedule is updated on the first day of each month and is also available at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

- 15406W **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial (*Benzylpenicillin benzathine (Brancaster Pharma, UK)*)

Alterations

Alteration – Note

- 15053G **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (& inert substance diluent [4 mL ampoule], 1 pack (*Lentocilin S 1200 (Portugal)*)
- 11755Q **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes (*Bicillin L-A*)

General Pharmaceutical Benefits

Additions

Addition – Item

- 15414G **ADRENALINE (EPINEPHRINE)**, Adrenaline (epinephrine) 1 mg/actuation nasal spray, 2 x 1 actuation (*neffy*)
- 15404R **ADRENALINE (EPINEPHRINE)**, Adrenaline (epinephrine) 2 mg/actuation nasal spray, 2 x 1 actuation (*neffy*)
- 15376G **ALECTINIB**, alectinib 150 mg capsule, 4 x 56 (*Alecensa*)
- 15365Q **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial (*Benzylpenicillin benzathine (Brancaster Pharma, UK)*)
- 15389Y **BENZATHINE BENZYL PENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial (*Benzylpenicillin benzathine (Brancaster Pharma, UK)*)
- 15401N **FUTIBATINIB**, Futibatinib 4 mg tablet, 35 (*Lytgobi*)
- 15393E **INSULIN DEGLUDEC**, insulin degludec 100 units/mL injection, 5 x 3 mL cartridges (*Tresiba Penfill*)
- 15377H **METHADONE**, methadone hydrochloride 5 mg tablet, 20 (*METHADONE-AFT*)
- 15381M **MIDAZOLAM**, midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe (*Zyamis*)
- 15388X **MIDAZOLAM**, midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe (*Zyamis*)
- 15378J **OSIMERTINIB**, osimertinib 40 mg tablet, 30 (*Tagrisso*)
- 15392D **OSIMERTINIB**, osimertinib 80 mg tablet, 30 (*Tagrisso*)
- 15415H **PHENOBARBITAL**, phenobarbital 30 mg tablet, 100 (*Phenobarbital Tablets, USP 30 mg (Rising Pharmaceuticals, USA)*)
- 15371B **SELPERCATINIB**, Selpercatinib 40 mg tablet, 56 (*Retevmo*)
- 15416J **SELPERCATINIB**, Selpercatinib 80 mg tablet, 56 (*Retevmo*)
- 15366R **TENOFOVIR DISOPROXIL + EMTRICITABINE**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30 (*Tenofovir Disoproxil Emtricitabine Viatris 300/200*)

15383P	TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (<i>CIPLA TENOFOVIR + EMTRICITABINE 300/200, TENOFOVIR/EMTRICITABINE 300/200 APX, TENOFOVIR/EMTRICITABINE 300/200 ARX</i>)
15410C	TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30 (<i>Tenofovir/Emtricitabine Sandoz 301/200</i>)
15380L	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula powder for oral liquid, 400 g (<i>Monogen</i>)
15382N	UPADACITINIB , upadacitinib 30 mg modified release tablet, 28 (<i>Rinvoq</i>)
15368W	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Wezlana</i>)
15390B	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Wezlana</i>)
15397J	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Wezlana</i>)
15400M	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Wezlana</i>)

Addition – Brand

5468T	<i>Dutacor</i> , CR – DUTASTERIDE , dutasteride 500 microgram capsule, 30
13900N	<i>Dutacor</i> , CR – DUTASTERIDE , dutasteride 500 microgram capsule, 30
1598D	<i>ARX-Mercaptopurine</i> , XT – MERCAPTOPURINE , mercaptopurine monohydrate 50 mg tablet, 25
9449H	<i>Blooms The Chemist Sitagliptin/Metformin 50/500</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56
13994M	<i>Blooms The Chemist Sitagliptin/Metformin 50/500</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56
9450J	<i>Blooms The Chemist Sitagliptin/Metformin 50/850</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56
14064F	<i>Blooms The Chemist Sitagliptin/Metformin 50/850</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56
10090C	<i>Sitagliptin/Metformin XR KND</i> , CR – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56
13990H	<i>Sitagliptin/Metformin XR KND</i> , CR – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56
9451K	<i>Blooms The Chemist Sitagliptin/Metformin 50/1000</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56
14035Q	<i>Blooms The Chemist Sitagliptin/Metformin 50/1000</i> , BG – SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56
10089B	<i>Sitagliptin/Metformin XR KND</i> , CR – SITAGLIPTIN + METFORMIN , sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28
14031L	<i>Sitagliptin/Metformin XR KND</i> , CR – SITAGLIPTIN + METFORMIN , sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28
1418P	<i>Ticagrelor SUN</i> , RA – TICAGRELOR , ticagrelor 90 mg tablet, 56
13524T	<i>Ticagrelor SUN</i> , RA – TICAGRELOR , ticagrelor 90 mg tablet, 56
14877B	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14879D	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14890Q	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14891R	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14892T	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14898D	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14899E	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14908P	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14909Q	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14916C	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14933Y	<i>Wezlana</i> , AN – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14944M *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
9304Q *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
9305R *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
10767Q *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
10774C *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
11178H *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
12662K *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
12664M *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
12669T *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
13261Y *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
13273N *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
13789R *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
13805N *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14878C *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14893W *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14897C *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14907N *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14917D *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14918E *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14926N *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14934B *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14935C *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe
14943L *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe

Addition – Equivalence Indicator

1850J *Phenobarb, RW* – **PHENOBARBITAL**, phenobarbital 30 mg tablet, 200
14693H *Retevmo, LY* – **SELPERCATINIB**, selpercatinib 40 mg capsule, 56
14703W *Retevmo, LY* – **SELPERCATINIB**, selpercatinib 80 mg capsule, 56
14877B *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14879D *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14890Q *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14891R *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14892T *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14898D *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14899E *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14908P *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14909Q *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14916C *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14933Y *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
14944M *Steqeyma, EW* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe
9304Q *Stelara, JC* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
9305R *Stelara, JC* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
10767Q *Stelara, JC* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
10774C *Stelara, JC* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
11178H *Stelara, JC* – **USTEKINUMAB**, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12662K	<i>Stelara, JC</i> – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
12664M	<i>Stelara, JC</i> – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
12669T	<i>Stelara, JC</i> – USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial
14878C	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14893W	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14897C	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14907N	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14917D	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14918E	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14926N	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14934B	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14935C	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe
14943L	<i>Steqeyma, EW</i> – USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe

Addition – Note

1850J	PHENOBARBITAL , phenobarbital 30 mg tablet, 200 (<i>Phenobarb</i>)
14693H	SELPERCATINIB , selpercatinib 40 mg capsule, 56 (<i>Retevmo</i>) - Supply Only
14703W	SELPERCATINIB , selpercatinib 80 mg capsule, 56 (<i>Retevmo</i>) - Supply Only

Addition – Caution

8697R	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr.</i>)
8698T	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Viatris, Anapen 300, EpiPen</i>)
12655C	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device (<i>Anapen 500</i>)

Deletions

Deletion – Brand

5551E	<i>Bimtop, AF</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
8620Q	<i>Bimtop, AF</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
14315K	<i>Bimtop, AF</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
8362D	<i>Capecitabine Sandoz, SZ</i> – CAPECITABINE , capecitabine 500 mg tablet, 120
9483D	<i>EzSimva GH 10/10, GQ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
13385L	<i>EzSimva GH 10/10, GQ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
8887R	<i>Meloxicam Sandoz, SZ</i> – MELOXICAM , meloxicam 7.5 mg capsule, 30
8888T	<i>Meloxicam Sandoz, SZ</i> – MELOXICAM , meloxicam 15 mg capsule, 30
3050M	<i>Idaprex 2, SZ</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
13404L	<i>Idaprex 2, SZ</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
3051N	<i>Idaprex 4, SZ</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
13371R	<i>Idaprex 4, SZ</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
8704D	<i>Idaprex 8, SZ</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
13372T	<i>Idaprex 8, SZ</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
8449Q	<i>Idaprex Combi 4/1.25, SZ</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
13476G	<i>Idaprex Combi 4/1.25, SZ</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
1952R	<i>Rasagiline Sandoz, SZ</i> – RASAGILINE , rasagiline 1 mg tablet, 30

14458Y *Rasagiline Sandoz, SZ* – **RASAGILINE**, rasagiline 1 mg tablet, 30

Deletion – Equivalence Indicator

8362D *Xelabine, AL* – **CAPECITABINE**, capecitabine 500 mg tablet, 120
11366F *LINCOMYCIN SXP, XN* – **LINCOMYCIN**, lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules
11380Y *LINCOMYCIN SXP, XN* – **LINCOMYCIN**, lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

Deletion – Note

11366F **LINCOMYCIN**, lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules (*LINCOMYCIN SXP*)
11380Y **LINCOMYCIN**, lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules (*LINCOMYCIN SXP*)
9327X **MEDIUM CHAIN TRIGLYCERIDES**, medium chain triglycerides oral liquid, 250 mL bottle (*Liquigen*)
3128P **MEDIUM CHAIN TRIGLYCERIDES**, medium chain triglycerides oral oil, 500 mL (*MCT Oil*)
12948L **TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula oral liquid, 12 x 500 mL bottles (*Nutrini Peptisorb*)
1938B **TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula powder for oral liquid, 400 g (*Lipistart*)
10154K **TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula powder for oral liquid, 400 g (*Peptamen Junior*)
10155L **TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula powder for oral liquid, 400 g (*Lipistart*)

Deletion – Caution

8697R **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device (*Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr.*)
8698T **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (*Adrenaline Viatris, Anapen 300, EpiPen*)
12655C **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device (*Anapen 500*)

Alterations

Alteration – Note

12345R **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Hadlima, Humira, Hyrimoz, Yuflyma*)
12389C **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Hadlima, Humira, Hyrimoz, Yuflyma*)
12410E **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Hadlima, Humira, Hyrimoz, Yuflyma*)
12433J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Hadlima, Humira, Hyrimoz, Yuflyma*)
12451H **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Hadlima, Humira, Hyrimoz, Yuflyma*)
12453K **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Hadlima, Humira, Hyrimoz, Yuflyma*)
13219R **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Hadlima, Hyrimoz, Yuflyma*)
13225C **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Hadlima, Hyrimoz, Yuflyma*)
9188N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz*)
9189P **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz*)
9190Q **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz*)
9191R **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz*)
12352D **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz*)
12387Y **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz*)

12402R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Abrilada, Amgevita, Hadlima, Hyrimoz</i>)
12437N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz</i>)
12372E	ADALIMUMAB , adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (<i>Humira, Yuflyma</i>)
12419P	ADALIMUMAB , adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (<i>Humira, Hyrimoz, Yuflyma</i>)
8697R	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr.</i>)
8698T	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Viatris, Anapen 300, EpiPen</i>)
12655C	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device (<i>Anapen 500</i>)
15058M	BENZATHINE BENZYL PENICILLIN , benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (& inert substance diluent [4 mL ampoule], 1 pack (<i>Lentocilin S 1200 (Portugal)</i>))
15063T	BENZATHINE BENZYL PENICILLIN , benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (& inert substance diluent [4 mL ampoule], 1 pack (<i>Lentocilin S 1200 (Portugal)</i>))
2267H	BENZATHINE BENZYL PENICILLIN , benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes (<i>Bicillin L-A</i>)
5027N	BENZATHINE BENZYL PENICILLIN , benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes (<i>Bicillin L-A</i>)
12551N	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12560C	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12567K	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12585J	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12586K	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12597B	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
13768P	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)
13746L	UPADACITINIB , upadacitinib 30 mg modified release tablet, 28 (<i>Rinvoq</i>)
13762H	UPADACITINIB , upadacitinib 30 mg modified release tablet, 28 (<i>Rinvoq</i>)
13771T	UPADACITINIB , upadacitinib 45 mg modified release tablet, 28 (<i>Rinvoq</i>)
11178H	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara, Wezlana</i>)
14898D	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe (<i>Steqeyma, Wezlana</i>)
14909Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe (<i>Steqeyma, Wezlana</i>)
14926N	USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe (<i>Steqeyma, Wezlana</i>)
14934B	USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe (<i>Steqeyma, Wezlana</i>)
12620F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12638E	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12654B	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)

Alteration – Restriction

12345R	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
12389C	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
12410E	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
12433J	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
12451H	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
12453K	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Hadlima, Humira, Hyrimoz, Yuflyma</i>)
13219R	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Hadlima, Hyrimoz, Yuflyma</i>)

13225C	ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (<i>Hadlima, Hyrimoz, Yuflyma</i>)
9188N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz</i>)
9189P	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz</i>)
9190Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Abrilada, Amgevita, Hadlima, Hyrimoz</i>)
9191R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Abrilada, Amgevita, Hadlima, Hyrimoz</i>)
12352D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Abrilada, Amgevita, Hadlima, Hyrimoz</i>)
12387Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz</i>)
12402R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Abrilada, Amgevita, Hadlima, Hyrimoz</i>)
12437N	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz</i>)
12372E	ADALIMUMAB , adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (<i>Humira, Yuflyma</i>)
12419P	ADALIMUMAB , adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (<i>Humira, Hyrimoz, Yuflyma</i>)
15359J	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device (<i>Jext Jnr</i>)
8697R	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr.</i>)
8698T	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (<i>Adrenaline Viatris, Anapen 300, EpiPen</i>)
15355E	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (<i>Jext</i>)
12655C	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device (<i>Anapen 500</i>)
11226W	ALECTINIB , alectinib 150 mg capsule, 4 x 56 (<i>Alecensa</i>)
15337F	GLYCOPYRRONIUM , Glycopyrronium 2.2 mg/actuation cream, 124 actuations (<i>Axhidrox</i>)
12551N	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12560C	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12567K	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL pen device (<i>Remsima SC</i>)
12585J	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12586K	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
12597B	INFLIXIMAB , infliximab 120 mg/mL injection, 1 mL syringe (<i>Remsima SC</i>)
14292F	MIDAZOLAM , midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe (<i>Zyamis</i>)
14238J	MIDAZOLAM , midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe (<i>Zyamis</i>)
14270C	MIDAZOLAM , midazolam 10 mg/mL oral liquid, 1 mL syringe (<i>Zyamis</i>)
10154K	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula powder for oral liquid, 400 g (<i>Peptamen Junior</i>)
13768P	UPADACITINIB , upadacitinib 15 mg modified release tablet, 28 (<i>Rinvoq</i>)
13746L	UPADACITINIB , upadacitinib 30 mg modified release tablet, 28 (<i>Rinvoq</i>)
13762H	UPADACITINIB , upadacitinib 30 mg modified release tablet, 28 (<i>Rinvoq</i>)
13771T	UPADACITINIB , upadacitinib 45 mg modified release tablet, 28 (<i>Rinvoq</i>)
11178H	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara, Wezlana</i>)
12664M	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara, Wezlana</i>)
14891R	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe (<i>Steqeyma, Wezlana</i>)
14898D	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe (<i>Steqeyma, Wezlana</i>)
14909Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe (<i>Steqeyma, Wezlana</i>)
14926N	USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe (<i>Steqeyma, Wezlana</i>)

14934B	USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe (<i>Steqeyma, Wezlana</i>)
14943L	USTEKINUMAB , ustekinumab 90 mg/mL injection, 1 mL syringe (<i>Steqeyma, Wezlana</i>)
12620F	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12638E	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)
12654B	VEDOLIZUMAB , vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices (<i>Entyvio</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
10922W	<i>Nuvigil</i> – ARMODAFINIL , armodafinil 50 mg tablet, 30	TB	FW
10912H	<i>Nuvigil</i> – ARMODAFINIL , armodafinil 150 mg tablet, 30	TB	FW
10919Q	<i>Nuvigil</i> – ARMODAFINIL , armodafinil 250 mg tablet, 30	TB	FW
5457F	<i>CORORA</i> – DENOSUMAB , denosumab 60 mg/mL injection, 1 mL syringe	GV	XW
5457F	<i>Prolia</i> – DENOSUMAB , denosumab 60 mg/mL injection, 1 mL syringe	AN	XT
15001M	<i>Xgeva</i> – DENOSUMAB , denosumab 120 mg/mL injection, 1 mL syringe	AN	XT
15013E	<i>Xgeva</i> – DENOSUMAB , denosumab 120 mg/mL injection, 1 mL syringe	AN	XT
5110Y	<i>GANVADO</i> – DENOSUMAB , denosumab 120 mg/1.7 mL injection, 1.7 mL vial	GV	XW
10061M	<i>GANVADO</i> – DENOSUMAB , denosumab 120 mg/1.7 mL injection, 1.7 mL vial	GV	XW
5110Y	<i>Xgeva</i> – DENOSUMAB , denosumab 120 mg/1.7 mL injection, 1.7 mL vial	AN	XT
10061M	<i>Xgeva</i> – DENOSUMAB , denosumab 120 mg/1.7 mL injection, 1.7 mL vial	AN	XT
8816B	<i>Modavigil</i> – MODAFINIL , modafinil 100 mg tablet, 60	TB	FW

Supply Only

Supply Only – Period Commencing

11620N	OSIMERTINIB , osimertinib 40 mg tablet, 30 (<i>Tagrisso</i>)
12233W	OSIMERTINIB , osimertinib 40 mg tablet, 30 (<i>Tagrisso</i>)
14162J	OSIMERTINIB , osimertinib 40 mg tablet, 30 (<i>Tagrisso</i>)
11622Q	OSIMERTINIB , osimertinib 80 mg tablet, 30 (<i>Tagrisso</i>)
12232T	OSIMERTINIB , osimertinib 80 mg tablet, 30 (<i>Tagrisso</i>)
14168Q	OSIMERTINIB , osimertinib 80 mg tablet, 30 (<i>Tagrisso</i>)
14693H	SELPERCATINIB , Selpercatinib 40 mg capsule, 56 (<i>Retevmo</i>)
14703W	SELPERCATINIB , selpercatinib 80 mg capsule, 56 (<i>Retevmo</i>)
8478F	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula powder for oral liquid, 400 g (<i>Monogen</i>)
10152H	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula powder for oral liquid, 400 g (<i>Monogen</i>)

Supply Only – Period Ending

11245W	GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE , glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 27 g sachets (<i>PKU Sphere15</i>)
2530E	LINCOMYCIN , lincomycin 600 mg/2 mL injection, 5 x 2 mL vials (<i>Lincocin</i>)
5144R	LINCOMYCIN , lincomycin 600 mg/2 mL injection, 5 x 2 mL vials (<i>Lincocin</i>)
2481N	OXYCODONE , oxycodone 30 mg suppository, 12 (<i>Proladone</i>)
5194J	OXYCODONE , oxycodone 30 mg suppository, 12 (<i>Proladone</i>)
11286B	SAXAGLIPTIN + DAPAGLIFLOZIN , saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 (<i>Qtern 5/10</i>)
13855F	SAXAGLIPTIN + DAPAGLIFLOZIN , saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 (<i>Qtern 5/10</i>)

Advance Notices

1 August 2026

Deletion – Item

- 8409N *Qvar 100 Autohaler, IL* – **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations
- 14514X *Qvar 100 Autohaler, IL* – **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations
- 15076L *Clopidogrel Tablets, USP 75 mg (Novadoz, USA), KQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30
- 15081R *Clopidogrel Tablets, USP 75 mg (Aurobindo, USA), LM* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30
- 15085Y *Clopidogrel Tablets, USP 75 mg (Aurobindo, USA), LM* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30
- 15086B *Clopidogrel Tablets, USP 75 mg (Novadoz, USA), KQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30
- 1610R *Leucovorin Calcium (Pfizer Australia Pty Ltd), PF* – **FOLINIC ACID**, folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules
- 8027L *Minitrans 5, IL* – **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30
- 14371J *Minitrans 5, IL* – **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30
- 8084L *Humalog, LY* – **INSULIN LISPRO**, insulin lispro 100 units/mL injection, 1 x 10 mL vial
- 1426C *Humulin 30/70, LY* – **INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN**, insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial
- 15109F *Ritalin LA 10 mg (Switzerland), KQ* – **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30
- 15101T *Ritalin LA 20 mg (Switzerland), KQ* – **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30
- 15070E *Ritalin LA 30 mg (Switzerland), KQ* – **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 100
- 15099Q *Ritalin LA 30 mg (Switzerland), KQ* – **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30
- 15100R *Ritalin LA 40 mg (Switzerland), KQ* – **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30
- 9031H *Daktarin Tincture, JT* – **MICONAZOLE**, miconazole 2% solution, 30 mL

Deletion – Brand

- 3094W *Keflex, AS* – **CEFALEXIN**, cefalexin 125 mg/5 mL powder for oral liquid, 100 mL
- 3319Q *Keflex, AS* – **CEFALEXIN**, cefalexin 125 mg/5 mL powder for oral liquid, 100 mL
- 1533Q *Humulin NPH, LY* – **INSULIN ISOPHANE HUMAN**, insulin isophane human 100 units/mL injection, 1 x 10 mL vial
- 1531N *Humulin R, LY* – **INSULIN NEUTRAL HUMAN**, insulin neutral human 100 units/mL injection, 1 x 10 mL vial
- 1928L *Depo-Nisolone, FZ* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials
- 5148Y *Depo-Nisolone, FZ* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials
- 3382B *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 10 mg orally disintegrating tablet, 28
- 1944H *Ramipril Winthrop, WA* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30
- 13582W *Ramipril Winthrop, WA* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30
- 8380C *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5
- 8821G *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5
- 9361Q *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5
- 9362R *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

1 September 2026

Deletion – Item

- 1750D *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g
- 5522P *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

14493T *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

Deletion – Brand

1884E *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20
3301R *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20
11998L *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20
8533D *GLIMEPIRIDE-WGR, WG* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30
14020X *GLIMEPIRIDE-WGR, WG* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30
3385E *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 20 mg orally disintegrating tablet, 28
8695P *Actos, GQ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28
13921Q *Actos, GQ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

1 October 2026

Deletion – Brand

2604C *NOUMED ALLOPURINOL, VO* – **ALLOPURINOL**, allopurinol 300 mg tablet, 60
13575L *NOUMED ALLOPURINOL, VO* – **ALLOPURINOL**, allopurinol 300 mg tablet, 60
8655M *Levetiracetam Mylan, AL* – **LEVETIRACETAM**, levetiracetam 500 mg tablet, 60
14034P *Levetiracetam Mylan, AL* – **LEVETIRACETAM**, levetiracetam 500 mg tablet, 60

Palliative Care

Additions

Addition – Item

15412E **METHADONE**, methadone hydrochloride 5 mg tablet, 20 (*METHADONE-AFT*)

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

15362M **ROZANOLIXIZUMAB**, Rozanolixizumab 280 mg/2 mL injection, 2 mL vial (*Rystiggo*)
15375F **ROZANOLIXIZUMAB**, Rozanolixizumab 280 mg/2 mL injection, 2 mL vial (*Rystiggo*)
15363N **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device (*Tezspire*)
15364P **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device (*Tezspire*)

Addition – Brand

11164N *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial
13255P *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial
13804M *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial

Deletions

Deletion – Item

6480C **EPOETIN BETA**, epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
6481D **EPOETIN BETA**, epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
6482E **EPOETIN BETA**, epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
6483F **EPOETIN BETA**, epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
6484G **EPOETIN BETA**, epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
6485H **EPOETIN BETA**, epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes (*NeoRecormon*)
14213C **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)
14177E **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)
14201K **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)

Deletion – Brand

6100C	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
12784W	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13033Y	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13038F	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13039G	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13040H	AZACITIDINE EUGIA, YG – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6100C	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
12784W	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13033Y	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13038F	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13039G	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial
13040H	Azacitidine Sandoz, SZ – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Deletion – Note

6227R	OCTREOTIDE , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (<i>Octreotide GH, Octreotide (SUN), Sandostatin 0.05</i>)
6228T	OCTREOTIDE , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (<i>Octreotide GH, Octreotide (SUN), Sandostatin 0.1</i>)
6229W	OCTREOTIDE , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (<i>Octreotide GH, Octreotide (SUN), Sandostatin 0.5</i>)

Alterations**Alteration – Note**

11996J	BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL pen device (<i>Fasenra Pen</i>)
11997K	BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL pen device (<i>Fasenra Pen</i>)
11999M	BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL pen device (<i>Fasenra Pen</i>)
12313C	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12316F	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12294C	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
12310X	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
9613Y	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Ixifi, Remicade, Remsima, Renflexis</i>)
11396T	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Ixifi, Remsima, Renflexis</i>)
12043W	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
12051G	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
12052H	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
10110D	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
11826K	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
11840E	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
14904K	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
14919F	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo</i>)
14921H	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
14939G	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
10122R	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
11825J	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)

11864K	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14883H	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14923K	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14927P	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14928Q	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14912W	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
14951X	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
14953B	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
15234T	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15235W	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15263H	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15254W	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
15259D	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
15264J	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
11164N	USTEKINUMAB , ustekinumab 130 mg/26 mL injection, 26 mL vial (<i>Stelara, Steqeyma, Wezlana</i>)
10415E	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
14614E	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
15285L	ZILUCOPLAN , Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes (<i>Zilbrysq</i>)
15302J	ZILUCOPLAN , Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes (<i>Zilbrysq</i>)
15304L	ZILUCOPLAN , Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes (<i>Zilbrysq</i>)
15315C	ZILUCOPLAN , Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes (<i>Zilbrysq</i>)
15284K	ZILUCOPLAN , Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes (<i>Zilbrysq</i>)
15294Y	ZILUCOPLAN , Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes (<i>Zilbrysq</i>)

Alteration – Restriction

9648T	AMBRISENTAN , ambrisentan 5 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
12201E	AMBRISENTAN , ambrisentan 5 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
9649W	AMBRISENTAN , ambrisentan 10 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
12180C	AMBRISENTAN , ambrisentan 10 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
11997K	BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL pen device (<i>Fasenra Pen</i>)
6429J	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
12139X	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
12148J	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
6430K	BOSENTAN , bosentan 125 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan GH, Bosentan RBX, Bosentan Viatris</i>)
12146G	BOSENTAN , bosentan 125 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan GH, Bosentan RBX, Bosentan Viatris</i>)
12313C	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12310X	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
10111E	EPOPROSTENOL , epoprostenol 500 microgram injection, 1 vial (<i>Veletri</i>)
10129D	EPOPROSTENOL , epoprostenol 1.5 mg injection, 1 vial (<i>Veletri</i>)
6456T	ILOPROST , iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules (<i>Ventavis</i>)
9613Y	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remicade, Remsima, Renflexis</i>)
11396T	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remsima, Renflexis</i>)
10134J	MACITENTAN , macitentan 10 mg tablet, 30 (<i>Opsumit</i>)

12135Q	MACITENTAN , macitentan 10 mg tablet, 30 (<i>Opsumit</i>)
12051G	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
10110D	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
14904K	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
10122R	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14923K	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14953B	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
9605M	SILDENAFIL , sildenafil 20 mg tablet, 90 (<i>SILDATIO PHT, Sildenafil PHT APOTEX, SILDENAFIL PHT ARX, Sildenafil Sandoz PHT 20</i>)
12138W	SILDENAFIL , sildenafil 20 mg tablet, 90 (<i>SILDATIO PHT, Sildenafil PHT APOTEX, SILDENAFIL PHT ARX, Sildenafil Sandoz PHT 20</i>)
1304P	TADALAFIL , tadalafil 20 mg tablet, 56 (<i>Adcirca, Tadalca, TADALIS 20</i>)
12150L	TADALAFIL , tadalafil 20 mg tablet, 56 (<i>Adcirca, Tadalca, TADALIS 20</i>)
14229X	TADALAFIL , tadalafil 20 mg tablet, 60 (<i>Tadalafil 20</i>)
14240L	TADALAFIL , tadalafil 20 mg tablet, 60 (<i>Tadalafil 20</i>)
11164N	USTEKINUMAB , ustekinumab 130 mg/26 mL injection, 26 mL vial (<i>Stelara, Steqeyma, Wezlana</i>)
10415E	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
14614E	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)

Supply Only

Supply Only – Period Commencing

11399Y	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remicade, Remsima, Renflexis</i>)

Supply Only – Period Ending

14804E	EDARAVONE , edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules (<i>Radicava</i>)

Advance Notices

1 August 2026

Deletion – Item

14296K	<i>Onpattro, WM</i> – PATISIRAN , patisiran 10 mg/5 mL injection, 5 mL vial

Deletion – Brand

9648T	<i>Cipla Ambrisentan, ZU</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30
12201E	<i>Cipla Ambrisentan, ZU</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30
6499C	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
11236J	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
11241P	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
6500D	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28
11238L	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28
11244T	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

15391C	ROZANOLIXIZUMAB , Rozanolixizumab 280 mg/2 mL injection, 2 mL vial (<i>Rystiggo</i>)
15398K	ROZANOLIXIZUMAB , Rozanolixizumab 280 mg/2 mL injection, 2 mL vial (<i>Rystiggo</i>)
15403Q	TEZEPELUMAB , Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device (<i>Tezspire</i>)
15413F	TEZEPELUMAB , Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device (<i>Tezspire</i>)

Addition – Brand

- 11182M *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial
13272M *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial
13781H *Wezlana, AN* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial

Deletions**Deletion – Item**

- 5724G **EPOETIN BETA**, epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
5725H **EPOETIN BETA**, epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
5726J **EPOETIN BETA**, epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
5727K **EPOETIN BETA**, epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
5728L **EPOETIN BETA**, epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes (*NeoRecormon*)
5729M **EPOETIN BETA**, epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes (*NeoRecormon*)
14178F **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)
14219J **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)
14218H **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL vials (*Octreotide Acetate Omega (Canada)*)

Deletion – Brand

- 9597D *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9598E *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
12771E *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13028Q *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13036D *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13042K *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13044M *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9597D *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9598E *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
12771E *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13028Q *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13036D *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13042K *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
13044M *Azacitidine Sandoz, SZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Deletion – Note

- 9508K **OCTREOTIDE**, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (*Octreotide GH, Octreotide (SUN), Sandostatin 0.05*)
9509L **OCTREOTIDE**, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (*Octreotide GH, Octreotide (SUN), Sandostatin 0.1*)
9510M **OCTREOTIDE**, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (*Octreotide GH, Octreotide (SUN), Sandostatin 0.5*)

Alterations**Alteration – Note**

- 11994G **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device (*Fasenra Pen*)
11995H **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device (*Fasenra Pen*)
12000N **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device (*Fasenra Pen*)
12309W **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (*Dupixent*)
12318H **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (*Dupixent*)

12293B	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
12302L	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
5754W	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remicade, Remsima, Renflexis</i>)
11400B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remsima, Renflexis</i>)
12007Y	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
12021Q	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
12064Y	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
10118M	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
11835X	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
11846L	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
14905L	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
14947Q	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo</i>)
14949T	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
14950W	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
10109C	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
11824H	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
11828M	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14884J	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14922J	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14929R	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14948R	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14885K	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
14906M	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
14952Y	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
15244H	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15245J	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15255X	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
15225H	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
15246K	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
15258C	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
11182M	USTEKINUMAB , ustekinumab 130 mg/26 mL injection, 26 mL vial (<i>Stelara, Steqeyma, Wezlana</i>)
10390W	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
14630B	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
15276B	ZILUCOPLAN , Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes (<i>Zilbrysq</i>)
15316D	ZILUCOPLAN , Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes (<i>Zilbrysq</i>)
15286M	ZILUCOPLAN , Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes (<i>Zilbrysq</i>)
15303K	ZILUCOPLAN , Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes (<i>Zilbrysq</i>)
15287N	ZILUCOPLAN , Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes (<i>Zilbrysq</i>)
15325N	ZILUCOPLAN , Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes (<i>Zilbrysq</i>)

Alteration – Restriction

5607D	AMBRISENTAN , ambrisentan 5 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
12212R	AMBRISENTAN , ambrisentan 5 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
5608E	AMBRISENTAN , ambrisentan 10 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)
12186J	AMBRISENTAN , ambrisentan 10 mg tablet, 30 (<i>Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris</i>)

11994G	BENRALIZUMAB , benralizumab 30 mg/mL injection, 1 mL pen device (<i>Fasenra Pen</i>)
5618Q	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
12134P	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
12145F	BOSENTAN , bosentan 62.5 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan RBX</i>)
5619R	BOSENTAN , bosentan 125 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan GH, Bosentan RBX, Bosentan Viatris</i>)
12149K	BOSENTAN , bosentan 125 mg tablet, 60 (<i>Bosentan APO, BOSENTAN DR.REDDY'S, Bosentan GH, Bosentan RBX, Bosentan Viatris</i>)
12309W	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12293B	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
10130E	EPOPROSTENOL , epoprostenol 500 microgram injection, 1 vial (<i>Velettri</i>)
10117L	EPOPROSTENOL , epoprostenol 1.5 mg injection, 1 vial (<i>Velettri</i>)
5751Q	ILOPROST , iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules (<i>Ventavis</i>)
5754W	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remicade, Remsima, Renflexis</i>)
11400B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remsima, Renflexis</i>)
10136L	MACITENTAN , macitentan 10 mg tablet, 30 (<i>Opsumit</i>)
12147H	MACITENTAN , macitentan 10 mg tablet, 30 (<i>Opsumit</i>)
12007Y	MEPOLIZUMAB , mepolizumab 100 mg/mL injection, 1 mL pen device (<i>Nucala</i>)
10118M	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Omlyclo, Xolair</i>)
14949T	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device (<i>Xolair</i>)
10109C	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Omlyclo</i>)
14884J	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL pen device (<i>Xolair</i>)
14885K	OMALIZUMAB , omalizumab 300 mg/2 mL injection, 2 mL pen device (<i>Xolair</i>)
9547L	SILDENAFIL , sildenafil 20 mg tablet, 90 (<i>SILDATIO PHT, Sildenafil PHT APOTEX, SILDENAFIL PHT ARX, Sildenafil Sandoz PHT 20</i>)
12144E	SILDENAFIL , sildenafil 20 mg tablet, 90 (<i>SILDATIO PHT, Sildenafil PHT APOTEX, SILDENAFIL PHT ARX, Sildenafil Sandoz PHT 20</i>)
1308W	TADALAFIL , tadalafil 20 mg tablet, 56 (<i>Adcirca, Tadalca, TADALIS 20</i>)
12151M	TADALAFIL , tadalafil 20 mg tablet, 56 (<i>Adcirca, Tadalca, TADALIS 20</i>)
14271D	TADALAFIL , tadalafil 20 mg tablet, 60 (<i>Tadalafil 20</i>)
14281P	TADALAFIL , tadalafil 20 mg tablet, 60 (<i>Tadalafil 20</i>)
11182M	USTEKINUMAB , ustekinumab 130 mg/26 mL injection, 26 mL vial (<i>Stelara, Steqeyma, Wezlana</i>)
10390W	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)
14630B	VEDOLIZUMAB , vedolizumab 300 mg injection, 1 vial (<i>Entyvio</i>)

Supply Only

Supply Only – Period Commencing

11389K	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra, Ixifi, Remicade, Remsima, Renflexis</i>)

Supply Only – Period Ending

14805F	EDARAVONE , edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules (<i>Radicava</i>)

Advance Notices

1 August 2026

Deletion – Item

14264R	<i>Onpattro, WM</i> – PATISIRAN , patisiran 10 mg/5 mL injection, 5 mL vial

Deletion – Brand

5607D	<i>Cipla Ambrisentan, ZU</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30

12212R	<i>Cipla Ambrisentan, ZU</i> – AMBRISENTAN , ambrisentan 5 mg tablet, 30
5654N	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
11235H	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
11247Y	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 125 mg dispersible tablet, 28
5655P	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28
11239M	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28
11240N	<i>Pharmacor Deferasirox, CR</i> – DEFERASIROX , deferasirox 250 mg dispersible tablet, 28

Highly Specialised Drugs Program (Community Access)

Supply Only

Supply Only – Period Ending

10349Q	ATAZANAVIR , atazanavir 200 mg capsule, 60 (<i>Reyataz</i>)
10321F	ATAZANAVIR , atazanavir 300 mg capsule, 30 (<i>Reyataz</i>)

Advance Notices

1 September 2026

Deletion – Brand

10311Q	<i>Lamivudine Alphapharm, AF</i> – LAMIVUDINE , lamivudine 300 mg tablet, 30

Botulinum Toxin Program

Alterations

Alteration – Restriction

11016T	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)

Growth Hormone Program

Additions

Addition – Item

15384Q	SOMAPACITAN , somapacitan 10 mg/1.5 mL injection, 1.5 mL pen device (<i>Sogroya</i>)
15385R	SOMAPACITAN , somapacitan 10 mg/1.5 mL injection, 1.5 mL pen device (<i>Sogroya</i>)
15367T	SOMAPACITAN , somapacitan 15 mg/1.5 mL injection, 1.5 mL pen device (<i>Sogroya</i>)
15374E	SOMAPACITAN , somapacitan 15 mg/1.5 mL injection, 1.5 mL pen device (<i>Sogroya</i>)
15394F	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>SciTropin A</i>)
15399L	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>SciTropin A</i>)
15417K	SOMATROPIN , somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge (<i>SciTropin A</i>)

Alterations

Alteration – Note

13119L	SOMATROGON , somatrogon 24 mg/1.2 mL injection, 1.2 mL pen device (<i>Ngenla</i>)
13130C	SOMATROGON , somatrogon 24 mg/1.2 mL injection, 1.2 mL pen device (<i>Ngenla</i>)
13120M	SOMATROGON , somatrogon 60 mg/1.2 mL injection, 1.2 mL pen device (<i>Ngenla</i>)
13125T	SOMATROGON , somatrogon 60 mg/1.2 mL injection, 1.2 mL pen device (<i>Ngenla</i>)

Alteration – Restriction

11493X	SOMATROPIN , somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device (<i>Genotropin GoQuick</i>)
11895C	SOMATROPIN , somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
13712Q	SOMATROPIN , somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge (<i>Saizen</i>)

- 11495B **SOMATROPIN**, somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device (*Genotropin GoQuick*)
- 13709M **SOMATROPIN**, somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge (*Saizen*)

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

- 15409B **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 2 cm x 45 cm ribbon, 5 (*Aquacel Ag+ Ribbon 413571*)
- 15373D **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 10 cm x 10 cm dressing, 10 (*Aquacel Ag+ Extra 413567*)
- 15396H **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 15 cm x 15 cm dressing, 5 (*Aquacel Ag+ Extra 413568*)
- 15372C **MAGNESIUM**, Magnesium 37.4 mg tablet, 120 (*A-WON Magnesium*)
- 15408Y **PANTHENOL**, panthenol conditioner, 250 g (*SebiRinse*)

Addition – Brand

- 4082W *A-WON Calcium 600, WN* – **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
- 4142B *A-WON Calcium 600, WN* – **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
- 14174B *A-WON Calcium 600, WN* – **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
- 14175C *A-WON Calcium 600, WN* – **CALCIUM**, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
- 4046Y *Dofidaz, JM* – **DICLOFENAC**, diclofenac sodium 3% gel, 25 g
- 10102Q *Dutasteride/Tamsulosin Lupin 500/400, GQ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 14184M *Dutasteride/Tamsulosin Lupin 500/400, GQ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 10102Q *Dutasteride/Tamsulosin Sandoz 500/400, SZ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 14184M *Dutasteride/Tamsulosin Sandoz 500/400, SZ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 4222F *MAYNE PHARMA 5FU, SZ* – **FLUOROURACIL**, fluorouracil 5% cream, 20 g
- 4591P *GAPENTIN, RF* – **GABAPENTIN**, gabapentin 100 mg capsule, 100
- 4592Q *GAPENTIN, RF* – **GABAPENTIN**, gabapentin 300 mg capsule, 100
- 4593R *GAPENTIN, RF* – **GABAPENTIN**, gabapentin 400 mg capsule, 100
- 4594T *GAPENTIN, RF* – **GABAPENTIN**, gabapentin 600 mg tablet, 100
- 10592L *A-WON DIARRHOEA RELIEF CAPSULES, WN* – **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 12
- 11135C *A-WON DIARRHOEA RELIEF CAPSULES, WN* – **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 20
- 10598T *Chemists' Own Osteo Relief Paracetamol, RF* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96
- 4596X *Tadalafil Sandoz Pharma, HX* – **TADALAFIL**, tadalafil 10 mg tablet, 4
- 4597Y *Tadalafil Sandoz Pharma, HX* – **TADALAFIL**, tadalafil 20 mg tablet, 4
- 13307J *Zopiclone GH, GQ* – **ZOPICLONE**, zopiclone 7.5 mg tablet, 14

Addition – Equivalence Indicator

- 4046Y *Solaraze 3% Gel, YN* – **DICLOFENAC**, diclofenac sodium 3% gel, 25 g
- 10102Q *Duodart 500ug/400ug, GK* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 14184M *Duodart 500ug/400ug, GK* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30
- 10592L *Gastrex, CR* – **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 12

Deletions

Deletion – Item

- 10105W **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 2 cm x 45 cm ribbon, 5 (*Aquacel Ag 403771*)
- 10097K **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 10 cm x 10 cm dressing, 10 (*Aquacel Ag 403708*)
- 10098L **DRESSING HYDROFIBRE WITH SILVER**, dressing hydrofibre with silver 15 cm x 15 cm dressing, 5 (*Aquacel Ag 403710*)

Deletion – Brand

- 10598T *Pharmacy Action OSTEO Relief 665, HQ* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96
- 4522B *Imovane, SW* – **ZOPICLONE**, zopiclone 7.5 mg tablet, 30
- 4522B *Zopiclone GH, GQ* – **ZOPICLONE**, zopiclone 7.5 mg tablet, 30

Prescriber Bag

■ BENZATHINE BENZYL PENICILLIN

Note Pharmaceutical benefits that have the brand Benzylpenicillin benzathine (Brancaster Pharma, UK) or the brand Lentocilin S 1200 (Portugal) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.

Note The listing is intended to provide treatment for syphilis in Aboriginal and Torres Strait Islander patients in non-remote areas.

benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial

15406W	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	10.00	*490.44	^a Benzylpenicillin benzathine (Brancaster Pharma, UK) [QY]

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack

15053G	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	10.00	*490.44	^a Lentocilin S 1200 (Portugal) [NG]

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

11755Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP MW	1.00	327.06	^a Bicillin L-A [PF]

General Pharmaceutical Benefits

■ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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) 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 increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12410E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Hadlima [RF] ^a Hyrimoz [SZ]	^a Humira [VE] ^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF]

■ ADALIMUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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) 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 increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12389C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Hadlima [RF]	^a Humira [VE]
						^a Hyrimoz [SZ]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9191R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Abrilada [PF]	^a Amgevita [XT]
						^a Hadlima [RF]	^a Hyrimoz [SZ]

■ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18721

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13225C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Hadlima [RF] ^a Yuflyma [EW]	^a Hyrimoz [SZ]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12352D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Abrilada [PF] ^a Hadlima [RF]	^a Amgevita [XT] ^a Hyrimoz [SZ]

■ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18721

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13219R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Hadlima [RF] ^a Yuflyma [EW]	^a Hyrimoz [SZ]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12437N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	495.79	25.00	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF]

■ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
 - (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
 - (c) if applicable, the date of the most recent clinical assessment; and
 - (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.
- If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. 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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12372E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*2042.73	25.00	^a Humira [VE]	^a Yuflyma [EW]

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12419P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*2042.73	25.00	^a Humira [VE] ^a Yuflyma [EW]	^a Hyrimoz [SZ]

■ ADALIMUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, or Continuing 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; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12451H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	^a Hadlima [RF] ^a Hyrimoz [SZ]	^a Humira [VE] ^a Yuflyma [EW]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12453K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	^a Hadlima [RF] ^a Hyrimoz [SZ]	^a Humira [VE] ^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9188N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	^a Amgevita [XT] ^a Hyrimoz [SZ]	^a Hadlima [RF]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12387Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	^a Amgevita [XT]	^a Hadlima [RF]
						^a Hyrimoz [SZ]	

■ ADALIMUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**

-
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, or Continuing 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; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12345R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	^a Hadlima [RF] ^a Hyrimoz [SZ]	^a Humira [VE] ^a Yuflyma [EW]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12433J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	^a Hadlima [RF] ^a Hyrimoz [SZ]	^a Humira [VE] ^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9190Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	^a Abrilada [PF] ^a Hadlima [RF]	^a Amgevita [XT] ^a Hyrimoz [SZ]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12402R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	^a Abrilada [PF] ^a Hadlima [RF]	^a Amgevita [XT] ^a Hyrimoz [SZ]

■ ADRENALINE (EPINEPHRINE)

Caution Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

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

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

adrenaline (epinephrine) 500 microgram/0.3 mL injection, 0.3 mL pen device

12655C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	0	0.00	*156.52	25.00	Anapen 500 [XT]

■ ADRENALINE (EPINEPHRINE)

Caution Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

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

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Population criteria:

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

Population criteria:

- Patient must be aged 4 years or older
- Patient must weigh 15 kg or more.

Adrenaline (epinephrine) 1 mg/actuation nasal spray, 2 x 1 actuation

15414G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	0	0.00	171.25	25.00	neffy [CS]

Adrenaline (epinephrine) 2 mg/actuation nasal spray, 2 x 1 actuation

15404R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	0	0.00	171.25	25.00	neffy [CS]

■ ADRENALINE (EPINEPHRINE)

Caution Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

Note Pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device and pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device 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) or by telephone by contacting Services Australia on 1800 888 333.

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8697R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	0	0.00	*156.52	25.00	^a Adrenaline Jr Viatris [AF]	^a Anapen Junior 150 [XT]
						^a EpiPen Jr. [AL]	

■ ADRENALINE (EPINEPHRINE)

Caution Adrenaline products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The adrenaline devices should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au).

Note Pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Adrenaline Viatris, Anapen 300 and EpiPen) and pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Jext) 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) or by telephone by contacting Services Australia on 1800 888 333.

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

8698T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	0	0.00	*156.52	25.00	^a Adrenaline Viatrix [AF]	^a Anapen 300 [XT]
						^a EpiPen [AL]	

■ ADRENALINE (EPINEPHRINE)

Caution Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Adrenaline Viatrix, Anapen 300 and EpiPen) and pharmaceutical benefits that have the form adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device (Jext) 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) or by telephone by contacting Services Australia on 1800 888 333.

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

15355E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	0	0.00	*156.52	25.00	^a Jext [KB]

ADRENALINE (EPINEPHRINE)

Caution Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device and pharmaceutical benefits that have the form adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device 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) or by telephone by contacting Services Australia on 1800 888 333.

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

Note No applications for repeats will be authorised.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; **OR**
- Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis.

Authority Required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for any form of this drug for this indication.

adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device

15359J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	0	0.00	*156.52	25.00	^a Jext Jnr [KB]

ALECTINIB

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

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

Resected non-small cell lung cancer (NSCLC)

Treatment Phase: Adjuvant therapy

Clinical criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with an Anaplastic Lymphoma Kinase-Tyrosine Kinase Inhibitor (ALK-TKI) for non-small cell lung cancer; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**

- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with ALK-TKI at the time this drug was initiated, **AND**
- The condition must be/have been at least one of: (i) node positive, (ii) at least 4 cm in size, **AND**
- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 24 months of combined non-PBS and PBS-subsidised treatment for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred, **AND**
- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.

alectinib 150 mg capsule, 4 x 56

15376G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	0.00	6579.20	25.00	Alecensa [RO]

■ ALECTINIB

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

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

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with alectinib as adjuvant therapy in resected non-small cell lung cancer, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

Treatment criteria:

- Must be treated by a medical practitioner.

Authority Required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this indication (i.e. for stage IIIB/IV NSCLC), **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.

alectinib 150 mg capsule, 4 x 56

11226W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	0.00	6579.20	25.00	Alecensa [RO]

■ BENZATHINE BENZYL PENICILLIN

Note Pharmaceutical benefits that have the brand Benzylpenicillin benzathine (Brancastra Pharma, UK) or the brand Lentocilin S 1200 (Portugal) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.

benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial

15365Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	10	0	0.00	*490.44	25.00	^a Benzylpenicillin benzathine (Brancaster Pharma, UK) [QY]

benzathine benzylpenicillin 1.2 million units powder for injection, 1 vial

15389Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	0	0.00	*490.44	25.00	^a Benzylpenicillin benzathine (Brancaster Pharma, UK) [QY]

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack

15058M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	10	0	0.00	*490.44	25.00	^a Lentocilin S 1200 (Portugal) [NG]

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack

15063T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	0	0.00	*490.44	25.00	^a Lentocilin S 1200 (Portugal) [NG]

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

2267H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	0	0.00	327.06	25.00	^a Bicillin L-A [PF]

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

5027N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	0	0.00	327.06	25.00	^a Bicillin L-A [PF]

■ FUTIBATINIB

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)**18828**

Locally advanced or metastatic cholangiocarcinoma

Clinical criteria:

- Patient must have evidence of a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement at treatment initiation, **AND**
- Patient must have/have had received at least one line of systemic therapy prior to treatment initiation, **AND**
- Patient must have/have had a World Health Organisation (WHO) performance status of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Futibatinib 4 mg tablet, 35

15401N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	0.00	*16717.28	25.00	Lytgobi [TJ]

■ GLYCOPYRRONIUM

Caution The anticholinergic effect of this medicine may exacerbate pre-existing medical conditions including but not limited to cardiac arrhythmias.

Authority Required (STREAMLINED)**18870**

Severe primary axillary hyperhidrosis

Clinical criteria:

- Patient must have previously failed topical aluminium chloride after one to two months of treatment; **OR**
- Patient must be intolerant to topical aluminium chloride treatment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Glycopyrronium 2.2 mg/actuation cream, 124 actuations

15337F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	0.00	156.24	25.00	Axhidrox [KT]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive), **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

infliximab 120 mg/mL injection, 1 mL pen device

12567K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	0	0.00	*562.18	25.00	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12597B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	0	0.00	*738.30	25.00	Remsima SC [EW]

■ INFLIXIMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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. 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)

18869

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **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; **OR**

- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as 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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not 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 targeted therapy 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.

infliximab 120 mg/mL injection, 1 mL pen device

12560C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	0.00	*562.18	25.00	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12586K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	0.00	*738.30	25.00	Remsima SC [EW]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of supply listing - apply under this listing if the treatment phase is yet to be completed; the following prescription is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a patient is demonstrating a response to 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) 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.

Authority Required

Severe Crohn disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received treatment with the IV formulation of this drug for this condition; **OR**
- Patient must have received an approved PBS authority prescription for treatment with the IV formulation of this drug for this condition; **OR**
- Patient must not have received treatment with the IV formulation of this drug, but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation for this condition.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

The following information must be provided for patients who have not received the IV formulation as loading dose(s), but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation:

- (i) reason for loading doses being omitted; and
- (ii) if applicable, details of prior systemic therapy [dosage, date of commencement and duration of therapy]; and
- (iii) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (iv) if applicable, details of intestinal inflammation marker/s; and
- (v) if applicable, the PCDAI or CDAI score and the date of assessment; and
- (vi) the date of the most recent clinical assessment.

infliximab 120 mg/mL injection, 1 mL pen device

12551N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	0.00	*562.18	25.00	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12585J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	0.00	*738.30	25.00	Remsima SC [EW]

■ INSULIN DEGLUDEC

Note Special Pricing Arrangements apply.

Restricted benefit

Type 1 diabetes

insulin degludec 100 units/mL injection, 5 x 3 mL cartridges

15393E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	0.00	*370.79	25.00	Tresiba Penfill [NO]

■ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority Required (STREAMLINED)

15996

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority Required (STREAMLINED)

15994

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority Required (STREAMLINED)

16000

Chronic severe disabling pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 5 mg tablet, 20

15377H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	0	0.00	23.39	24.93	METHADONE-AFT [AE]

■ **MIDAZOLAM**

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

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

Authority Required

Generalized convulsive status epilepticus

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have been assessed to be at significant risk of status epilepticus, **AND**
- Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years.

Population criteria:

- Patient must be at least six months of age.

Clinical criteria:

- The treatment must be initiated by a specialist physician experienced in the treatment of epilepsy.

At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe

15388X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	0.00	*272.20	25.00	Zyamis [IX]

midazolam 5 mg/0.5 mL oral liquid, 0.5 mL syringe

14292F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	0.00	*272.20	25.00	Zyamis [IX]

midazolam 7.5 mg/0.75 mL oral liquid, 0.75 mL syringe

14238J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	0.00	*272.20	25.00	Zyamis [IX]

midazolam 10 mg/mL oral liquid, 1 mL syringe

14270C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	0.00	*272.20	25.00	Zyamis [IX]

■ MIDAZOLAM

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

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

Authority Required

Generalized convulsive status epilepticus

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances.

Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.

midazolam 2.5 mg/0.25 mL oral liquid, 0.25 mL syringe

15381M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	1	0.00	*272.20	25.00	Zyamis [IX]

■ OSIMERTINIB

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

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

Non-small cell lung cancer (NSCLC)

Clinical criteria:

- Patient must be each of: (i) initiating treatment with this drug; (ii) have not previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be continuing treatment with this drug for this condition, with an absence of further disease progression while being treated with this drug, **AND**
- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

Population criteria:

- Patient must not have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation.

Treatment criteria:

- Must be treated by a medical practitioner; **OR**
- Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.

PBS-subsidised treatment with this drug is restricted to once per lifetime at any disease stage for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Prescribers must refer to this drug's approved Therapeutic Goods Administration (TGA) Product Information (PI) for the relevant dosing regimens and treatment duration for the specific stage of NSCLC.

For patients receiving treatment with this drug as adjuvant therapy, treatment must cease upon disease progression, or after the completion of three years from the first administered dose, whichever comes first.

osimertinib 40 mg tablet, 30

15378J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	0.00	7700.25	25.00	Tagrisso [AP]

osimertinib 80 mg tablet, 30

15392D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	0.00	7700.25	25.00	Tagrisso [AP]

■ PHENOBARBITAL

Note Pharmaceutical benefits that have the brand Phenobarbital Tablets, USP 30 mg (Rising Pharmaceuticals, USA) can be substituted for Phenobarb in the case of a shortage.

Restricted benefit

Epilepsy

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.

phenobarbital 30 mg tablet, 200

1850J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	4	0.00	19.80	21.34	^a Phenobarb [RW]

phenobarbital 30 mg tablet, 100

15415H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	0.00	*225.84	25.00	^a Phenobarbital Tablets, USP 30 mg (Rising Pharmaceuticals, USA) [DZ]

■ SELPERCATINIB

Note Pharmaceutical benefits that have the forms Selpercatinib 40 mg tablet and Selpercatinib 40 mg capsule are equivalent for the purposes of substitution.

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)**16270**

Locally advanced or metastatic non-small cell lung cancer

Clinical criteria:

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Selpercatinib 40 mg tablet, 56

15371B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	0.00	2146.86	25.00	^a Retevmo [LY]

■ SELPERCATINIB

Note Pharmaceutical benefits that have the forms Selpercatinib 80 mg tablet and Selpercatinib 80 mg capsule are equivalent for the purposes of substitution.

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)**16282**

Locally advanced or metastatic non-small cell lung cancer

Clinical criteria:

- The condition must have evidence of rearranged during transfection (RET) gene fusion in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Medical practitioners may prescribe selpercatinib 80 mg with a quantity of up to 56 units where the dose does not exceed 120 mg twice daily (i.e., in combination with selpercatinib 40 mg). Selpercatinib 80 mg with a quantity of 112 units must be prescribed only where the dose is 160 mg twice daily to provide 28 days of treatment per dispensing. Prescribers should refer to the TGA PI for dosing and dose adjustments regimens.

Selpercatinib 80 mg tablet, 56

15416J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	0.00	*8213.36	25.00	^a Retevmo [LY]

▪ 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 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.

Restricted benefit

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued: (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

15366R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	0.00	*56.08	25.00	^a Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL]

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

15383P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	0.00	*56.08	25.00	^a CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR]	^a TENOFOVIR/EMTRICITABINE 300/200 APX [XW]
						^a TENOFOVIR/EMTRICITABINE 300/200 ARX [XT]	

tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30

15410C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	0.00	*56.08	25.00	^a Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; **OR**
- Patient must have fat malabsorption due to short gut syndrome; **OR**
- Patient must have fat malabsorption due to cystic fibrosis; **OR**
- Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula powder for oral liquid, 400 g

10154K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	0.00	*258.44	25.00	Peptamen Junior [NT]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; **OR**
- Patient must have fat malabsorption due to short gut syndrome; **OR**
- Patient must have fat malabsorption due to cystic fibrosis; **OR**
- Patient must have fat malabsorption due to gastrointestinal disorders.

Restricted benefit

Hyperlipoproteinaemia type 1

Restricted benefit

Long chain fatty acid oxidation disorders

Restricted benefit

Chylous ascites

Restricted benefit

Chylothorax

triglycerides medium chain formula powder for oral liquid, 400 g

15380L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	0.00	*393.32	25.00	Monogen [SB]

■ UPADACITINIB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Extended induction period (optional) from weeks 12 to 24

Clinical criteria:

- Patient must must have experienced an inadequate therapeutic benefit following the initial 12-week induction period.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

upadacitinib 30 mg modified release tablet, 28

13762H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	0.00	1983.58	25.00	Rinvoq [VE]

■ UPADACITINIB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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; **OR**
- The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Continuing (maintenance) treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

upadacitinib 30 mg modified release tablet, 28

13746L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	0.00	1983.58	25.00	Rinvoq [VE]

■UPADACITINIB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing (maintenance) treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Continuing (maintenance) treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

upadacitinib 15 mg modified release tablet, 28

13768P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	0.00	1203.55	25.00	Rinvoq [VE]

■ UPADACITINIB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with targeted therapy)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 12 weeks of treatment with upadacitinib may be requested under the Balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or extended induction restriction (Initial 1, Initial 2, Initial 3, or Extended induction period (optional) treatment), **AND**
- The treatment must provide no more than the balance of up to 12 weeks therapy available under Initial 1, 2 or 3 treatment restriction or the Extended induction period (optional) from weeks 12 to 24 treatment restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

upadacitinib 30 mg modified release tablet, 28

15382N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	0.00	1983.58	25.00	Rinvoq [VE]

upadacitinib 45 mg modified release tablet, 28

13771T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	0.00	2608.01	25.00	Rinvoq [VE]

■ USTEKINUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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. 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)

18721

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14909Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	0.00	*1579.14	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

15397J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	0.00	*1579.14	25.00	Wezlana [AN]

ustekinumab 90 mg/mL injection, 1 mL syringe

14926N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	986.28	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

■ USTEKINUMAB

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:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,
- 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 Any queries concerning the arrangements to 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)

16854

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 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).

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.

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.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

15368W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	794.25	25.00	Wezlana [AN]

■ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept 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 is receiving PBS-subsidised treatment for severe chronic plaque psoriasis 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.

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.

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 prescribed 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 times 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 times 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.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) 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); or

(iii) 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 or recommence with the same biological medicine within the same treatment cycle (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

(iv) 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).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, 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 Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

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.

(4) Swapping therapy.

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 the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

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 that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive 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 must be demonstrated based on the baseline PASI assessment provided 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 provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to 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.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note Any queries concerning the arrangements to 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)

16886

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority Required (STREAMLINED)

16911

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

15390B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	794.25	25.00	Wezlana [AN]

■ USTEKINUMAB

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 Any queries concerning the arrangements to 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)

16835

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 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.

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 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)

16967

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 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.

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 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.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

15400M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	794.25	25.00	Wezlana [AN]

■ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept 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 is receiving PBS-subsidised treatment for severe chronic plaque psoriasis 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.

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.

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 prescribed 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 times 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 times 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.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) 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); or

(iii) 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 or recommence with the same biological medicine within the same treatment cycle (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

(iv) 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).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, 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 Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

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.

(4) Swapping therapy.

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 the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

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 that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive 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 must be demonstrated based on the baseline PASI assessment provided 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 provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to 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.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted 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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

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

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14891R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	0.00	794.25	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

ustekinumab 90 mg/mL injection, 1 mL syringe

14943L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	0.00	986.28	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

■ USTEKINUMAB

Note TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept 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 is receiving PBS-subsidised treatment for severe chronic plaque psoriasis 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.

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.

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 prescribed 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 times 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 times 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.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naïve patient); or

(ii) 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); or

(iii) 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 or recommence with the same biological medicine within the same treatment cycle (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

(iv) 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).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

- (i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
- (ii) the patient has a current PASI score greater than 15

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

- (i) all subscores are rated moderate to severe; or
 - (ii) 2 of the three subscores are rated severe to very severe; or
 - (iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or
 - (iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,
- (2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for First continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, 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 Ustekinumab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks per continuing treatment course under the First continuing treatment restriction with that drug, provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks under the Subsequent continuing treatment restriction with that drug, provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

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.

(4) Swapping therapy.

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 the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

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 that biological medicine more than once within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive 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 must be demonstrated based on the baseline PASI assessment provided 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 provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to adalimumab or ustekinumab the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to 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.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Note For the next authority approval following this one, aim to conduct and submit the PASI assessment at approximately 4 weeks prior to when a new authority application is due to ensure uninterrupted 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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

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

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment, **AND**

- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

- (1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Whole body)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

- (1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment (Face, hand, foot)

Treatment criteria:

- Must be treated by a dermatologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy; **OR**
- The treatment must be in combination with methotrexate, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

- (1) details of the proposed prescription(s); 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 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 assessment of response to treatment must be provided in this application and documented in the patient's medical records.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

12664M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	0.00	794.25	25.00	^a Stelara [JC]	^a Wezlana [AN]

■ USTEKINUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient 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; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe

14898D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*1579.14	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

ustekinumab 90 mg/mL injection, 1 mL syringe

14934B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	986.28	25.00	^a Steqeyma [EW]	^a Wezlana [AN]

■ USTEKINUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend treatment beyond 24 weeks.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

A maximum number of repeats of this drug consisting of up to 1 repeat for patients whose dosing frequency is every 12 weeks and up to 2 repeats for patients whose dosing frequency is every 8 weeks, will be authorised.

Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by applying through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient 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; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

11178H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*1579.14	25.00	^a Stelara [JC]	^a Wezlana [AN]

VEDOLIZUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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 Special Pricing Arrangements apply.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment) with the subcutaneous form, **AND**
- The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under either 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 or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12620F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	0	0.00	1663.81	25.00	Entyvio [TK]

▪ **VEDOLIZUMAB**

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAl score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 must request sufficient quantity for up to 24 weeks of treatment under this restriction.

If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12654B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	0.00	1663.81	25.00	Entyvio [TK]

■ VEDOLIZUMAB**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

use when the patient has never received a targeted therapy for this indication. **Initial 1** - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months. **Initial 2** - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

use when treatment is resuming after an absence of PBS subsidy for at least 12 months. **Initial 3** - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program). **Transitioning from non-PBS supply commenced as a paediatric patient** - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority

applications. **Continuing treatment** - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated. **Balance of supply** - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Special Pricing Arrangements apply.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) 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; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

vedolizumab 108 mg/0.68 mL injection, 2 x 0.68 mL pen devices

12638E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	0	0.00	1663.81	25.00	Entyvio [TK]

Palliative Care

■ METHADONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note This treatment is not recommended for use in ambulant patients.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority Required

Severe disabling pain

Clinical criteria:

- Patient must not be opioid naive, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

methadone hydrochloride 5 mg tablet, 20

15412E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	0	0.00	*39.87	25.00	METHADONE-AFT [AE]

Highly Specialised Drugs Program (Private Hospital)

■ 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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 5 mg tablet, 30

9648T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1268.99	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

ambrisentan 10 mg tablet, 30

9649W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1268.99	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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 5 mg tablet, 30

12201E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1268.99	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

ambrisentan 10 mg tablet, 30

12180C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1268.99	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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	0	0.00	3194.69	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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);

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

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

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) 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 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	0.00	3194.69	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 all eligible 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) 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); 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	0.00	3194.69	Fasenra Pen [AP]

■ 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: 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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 62.5 mg tablet, 60

12139X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	131.47	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]

12139X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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.

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 therapy 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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 therapy 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) 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) 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 62.5 mg tablet, 60

6429J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	131.47	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a Bosentan RBX [RA]	

bosentan 125 mg tablet, 60

6430K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	131.47	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a Bosentan GH [GQ]	^a Bosentan RBX [RA]
					^a Bosentan Viatrix [AL]	

■ 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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) 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	0.00	131.47	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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	0.00	131.47	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a Bosentan GH [GQ]	^a Bosentan RBX [RA]
					^a Bosentan Viatris [AL]	

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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); 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

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

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) 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 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 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	0.00	1659.10	Dupixent [SW]

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	0.00	1659.10	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 all eligible 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) 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) 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); 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) 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 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	0.00	1659.10	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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

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

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 all eligible 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) 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); 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

12313C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	0.00	1659.10	Dupixent [SW]

▪ **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:

- 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).

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

- 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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) 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) 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) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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 that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH 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: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **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) 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 the prostanoid agent 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) 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) 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 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	0.00	*1047.54	Veletri [JC]

epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	0.00	*1829.04	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) 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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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) 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) 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) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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 that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH 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: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **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) 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 the prostanoid agent 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) 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) 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	0.00	372.81	Ventavis [BN]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18868

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not 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 targeted therapy 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	0.00	*977.29	^a Inflectra [PF]	^a Ixifi [FZ]
					^a Remsima [EW]	^a Renflexis [OQ]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they

have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

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 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under the Initial 1, 2 or 3 restrictions to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient treatment with this drug for this condition under the Continuing restriction to complete 24 weeks of treatment (8-weekly infusion regimen), **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

9613Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	202.85	^a Inflectra [PF]	^a Ixifi [FZ]
					^a Remicade [JC]	^a Remsima [EW]

9613Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^a Renflexis [OQ]						

■ 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	2348.49	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.

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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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	0.00	2348.49	Opsumit [JC]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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	0	0.00	1605.34	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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); 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

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

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) 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 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	0.00	1605.34	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 Re commencement 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 all eligible 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) 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); 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	0.00	1605.34	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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 300 mg/2 mL injection, 2 mL pen device

14912W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	444.11	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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) 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 150 mg/mL injection, 1 mL syringe

11825J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	223.46	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14883H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	226.67	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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) 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	Brand Name and Manufacturer
	1	0	0.00	116.35	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14939G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	117.96	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

Note Any queries concerning the arrangements to 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)

16949

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).

For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. 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 following information 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

14919F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	116.35	Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL syringe

14927P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	223.46	Omlyclo [EW]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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) 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 300 mg/2 mL injection, 2 mL pen device

14951X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	444.11	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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 300 mg/2 mL injection, 2 mL pen device

14953B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	444.11	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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 Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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) 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	Brand Name and Manufacturer
	1	5	0.00	116.35	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14921H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	117.96	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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 Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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) 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 150 mg/mL injection, 1 mL syringe

11864K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	223.46	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14928Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	226.67	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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

10110D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	7	0.00	116.35	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14904K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	117.96	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	223.46	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14923K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	226.67	^a Xolair [NV]

■ 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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**

- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have received a loading dose of this drug for this indication; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15235W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	0.00	6623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15264J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	0.00	24154.35	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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- azathioprine,
- ciclosporin,
- cyclophosphamide,
- methotrexate,
- mycophenolate
- tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

(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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Non-loading/maintenance doses)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 March 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);
- (c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

ravulizumab 300 mg/3 mL injection, 3 mL vial

15234T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	6623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15254W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	24154.35	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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**

- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

Authority Required

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication ('bridging therapy for gMG').

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

- (a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);
- (b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

-
- (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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**

- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15263H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	6623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15259D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	24154.35	Ultomiris [XI]

■ ROZANOLIXIZUMAB

Note Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

(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).

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15362M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	1	0.00	*219238.80	Rystiggo [UC]

■ ROZANOLIXIZUMAB

Note Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

-
- (1) Three months of acute treatment - 'acute severe gMG'.
 - (2) Six months of bridging therapy - 'bridging therapy for gMG'.
 - (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

(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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15375F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	2	0.00	*219238.80	Rystiggo [UC]

▪ **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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	109.05	^a SILDATIO PHT [RW]	^a Sildenafil PHT APOTEX [TY]
					^a SILDENAFIL PHT ARX [XT]	^a 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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	109.05	^a SILDATIO PHT [RW]	^a Sildenafil PHT APOTEX [TY]
					^a SILDENAFIL PHT ARX [XT]	^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	503.80	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	539.13	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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	503.80	^a Adcirca [LY]	^a Tadalca [CR]
					^a 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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	539.13	Tadalafil 20 [LR]

■ **TEZEPELUMAB**

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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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); 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

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

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

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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 and should be conducted within 4 weeks of the last dose of biological medicine.

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.

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 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.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15364P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	1721.02	Tezspire [AP]

■ TEZEPELUMAB**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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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); 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

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

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

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 blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiating treatment with this drug that has past or current evidence of atopy, documented by either: (i) skin prick testing; or (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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 month prior to initiating this drug, **AND**

(b) while receiving optimised asthma therapy in the 12 months prior to initiating this drug, 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 all eligible 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 tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four 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 (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.

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 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 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 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 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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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. 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 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four 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) 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).

Authority Required

Uncontrolled severe asthma

Treatment Phase: Grandfathering arrangements - Transitioning from non-PBS to PBS-subsidised 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 non-PBS-subsidised treatment with this biological medicine for this PBS indication prior to 1 July 2026, **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 had 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 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiation of non-PBS subsidised treatment with this drug for this condition that had past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 month prior to starting treatment with this drug, **AND**
- (b) while receiving optimised asthma therapy in the 12 months prior to starting treatment with this drug, 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 all eligible 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 tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

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.

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).

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.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15363N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	1721.02	Tezspire [AP]

■ USTEKINUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11164N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	0	0.00	*2292.16	^a Stelara [JC]	^a Steqeyma [EW]
					^a Wezlana [AN]	

VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they

have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Initial 4 (additional dose at week 10)

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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

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.

vedolizumab 300 mg injection, 1 vial

14614E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	2851.67	Entyvio [TK]

▪VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Special Pricing Arrangements apply.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility

requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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; **OR**

- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient 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 or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

vedolizumab 300 mg injection, 1 vial

10415E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	2851.67	Entyvio [TK]

■ ZILUCOPLAN

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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- azathioprine,
- ciclosporin,
- cyclophosphamide,
- methotrexate,
- mycophenolate
- tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialed a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialed a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15302J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	21444.29	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15304L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	29570.29	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15294Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	41707.86	Zilbrysq [UC]

▪ **ZILUCOPLAN**

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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialed a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialed a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

- (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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

-
- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15285L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	21444.29	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15315C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	29570.29	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15284K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	41707.86	Zilbrysq [UC]

Highly Specialised Drugs Program (Public Hospital)

■ 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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 5 mg tablet, 30

5607D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1219.75	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

ambrisentan 10 mg tablet, 30

5608E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1219.75	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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 5 mg tablet, 30

12212R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1219.75	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

ambrisentan 10 mg tablet, 30

12186J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1219.75	^a Ambrisentan Viatris [AL] ^a PULMORIS [XT]	^a Cipla Ambrisentan [ZU] ^a Volibris [ZE]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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	0	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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);

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

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

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) 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 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	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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

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

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 all eligible 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) 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); 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

11994G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	0.00	3145.45	Fasenra Pen [AP]

■ 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: 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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 62.5 mg tablet, 60

12134P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	117.53	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]

12134P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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.

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 therapy 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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 therapy 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) 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) 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 62.5 mg tablet, 60

5618Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	117.53	^a Bosentan APO [GX] ^a Bosentan RBX [RA]	^a BOSENTAN DR.REDDY'S [RI]

bosentan 125 mg tablet, 60

5619R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	117.53	^a Bosentan APO [GX] ^a Bosentan GH [GQ] ^a Bosentan Viatrix [AL]	^a BOSENTAN DR.REDDY'S [RI] ^a 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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) 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	0.00	117.53	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a 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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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	0.00	117.53	^a Bosentan APO [GX]	^a BOSENTAN DR.REDDY'S [RI]
					^a Bosentan GH [GQ]	^a Bosentan RBX [RA]
					^a Bosentan Viatris [AL]	

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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); 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

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

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) 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 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 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	0.00	1609.86	Dupixent [SW]

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	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 all eligible 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) 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) 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); 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) 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 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	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 all eligible 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) 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); 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	0.00	1609.86	Dupixent [SW]

■ **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:

- 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).

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

- 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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) 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) 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) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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 that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH 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: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **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) 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 the prostanoid agent 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) 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) 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 500 microgram injection, 1 vial

10130E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	0.00	*998.40	Veletri [JC]

epoprostenol 1.5 mg injection, 1 vial

10117L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	0.00	*1779.90	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) 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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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) 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) 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) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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 that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH 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: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **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) 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 the prostanoid agent 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) 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) 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	0.00	349.59	Ventavis [BN]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialed and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18819

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not 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 targeted therapy 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	0.00	*930.80	^a Inflectra [PF]	^a Ixifi [FZ]
					^a Remsima [EW]	^a Renflexis [OQ]

■ INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they

have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

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 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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 per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under the Initial 1, 2 or 3 restrictions to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient treatment with this drug for this condition under the Continuing restriction to complete 24 weeks of treatment (8-weekly infusion regimen), **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

5754W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	186.16	^a Inflectra [PF]	^a Ixifi [FZ]
					^a Remicade [JC]	^a Remsima [EW]

5754W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
^a Renflexis [OQ]						

■ 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	2299.25	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.

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**
- 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; this combination therapy is treating a patient with at least WHO functional class III PAH; **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 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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

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) 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) 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	0.00	2299.25	Opsumit [JC]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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	0	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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); 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

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

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) 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 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	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

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 Re commencement 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 all eligible 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) 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); 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	0.00	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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) 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 300 mg/2 mL injection, 2 mL pen device

14952Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	418.14	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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) 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 150 mg/mL injection, 1 mL syringe

11828M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	205.98	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14929R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	209.07	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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) 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

11846L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	102.99	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14905L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	104.54	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

Note Any queries concerning the arrangements to 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)

16846

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).

For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. 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 following information 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

14947Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	102.99	Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL syringe

14948R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	205.98	Omlyclo [EW]

■ 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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) 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 300 mg/2 mL injection, 2 mL pen device

14906M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	418.14	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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 300 mg/2 mL injection, 2 mL pen device

14885K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	418.14	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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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 Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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) 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 150 mg/mL injection, 1 mL syringe

11824H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	205.98	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14922J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	209.07	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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); 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 Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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) 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	Brand Name and Manufacturer
	1	5	0.00	102.99	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14950W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	104.54	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device 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).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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 150 mg/mL injection, 1 mL syringe

10109C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	205.98	^a Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14884J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	209.07	^a 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 with each of the biological medicines they are eligible for, 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 eligible 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, 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

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).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device 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).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at 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

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 all eligible 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) 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); 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	Brand Name and Manufacturer
	1	7	0.00	102.99	^a Omlyclo [EW]	^a Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14949T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	104.54	^a Xolair [NV]

■ 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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**

- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have received a loading dose of this drug for this indication; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15255X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	0.00	6574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15246K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	0.00	24105.11	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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- azathioprine,
- ciclosporin,
- cyclophosphamide,
- methotrexate,
- mycophenolate
- tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

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The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialed a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialed a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

(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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Non-loading/maintenance doses)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an 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 dose of the drug, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 March 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);
- (c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

ravulizumab 300 mg/3 mL injection, 3 mL vial

15244H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	6574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15225H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	24105.11	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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

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The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**

- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

Authority Required

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication ('bridging therapy for gMG').

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

- (a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);
- (b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

-
- (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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**

- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA 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 TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15245J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	6574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15258C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	24105.11	Ultomiris [XI]

■ ROZANOLIXIZUMAB

Note Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- azathioprine,
- ciclosporin,
- cyclophosphamide,
- methotrexate,
- mycophenolate
- tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

(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).

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15398K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	1	0.00	*219189.60	Rystiggo [UC]

■ ROZANOLIXIZUMAB

Note Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxpX-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

-
- (1) Three months of acute treatment - 'acute severe gMG'.
 - (2) Six months of bridging therapy - 'bridging therapy for gMG'.
 - (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

(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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15391C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	2	0.00	*219189.60	Rystiggo [UC]

▪ **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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	95.81	^a SILDATIO PHT [RW]	^a Sildenafil PHT APOTEX [TY]
					^a SILDENAFIL PHT ARX [XT]	^a 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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	95.81	^a SILDATIO PHT [RW]	^a Sildenafil PHT APOTEX [TY]
					^a SILDENAFIL PHT ARX [XT]	^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	475.54	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a 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 treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) 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.

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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- 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) 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) 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	0.00	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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	475.54	^a Adcirca [LY]	^a Tadalca [CR]
					^a 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**
- 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; this combination therapy is treating a patient with at least class WHO functional class III PAH; **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

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see 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

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:

- 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; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **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 - the patient has WHO functional 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.

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) 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) 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; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **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) 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) 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	0.00	509.51	Tadalafil 20 [LR]

■ TEZEPELUMAB

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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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); 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

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

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

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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 and should be conducted within 4 weeks of the last dose of biological medicine.

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.

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 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.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15413F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	1671.78	Tezspire [AP]

■ TEZEPELUMAB**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 with each of the biological medicines they are eligible for, 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 eligible 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, 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 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); 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

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

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

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 blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiating treatment with this drug that has past or current evidence of atopy, documented by either: (i) skin prick testing; or (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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 month prior to initiating this drug, **AND**

(b) while receiving optimised asthma therapy in the 12 months prior to initiating this drug, 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 all eligible 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 tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four 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 (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.

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 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 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 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 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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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. 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 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four 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) 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).

Authority Required

Uncontrolled severe asthma

Treatment Phase: Grandfathering arrangements - Transitioning from non-PBS to PBS-subsidised 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 non-PBS-subsidised treatment with this biological medicine for this PBS indication prior to 1 July 2026, **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 had 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 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiation of non-PBS subsidised treatment with this drug for this condition that had past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **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 any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled 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 month prior to starting treatment with this drug, **AND**
- (b) while receiving optimised asthma therapy in the 12 months prior to starting treatment with this drug, 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 all eligible 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 tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

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.

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).

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.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15403Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	0.00	1671.78	Tezspire [AP]

■ USTEKINUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

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 targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

- (a) the baseline CDAI score and the date of assessment; and/or
- (b) details (date, unique identifying number/code or provider number) 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

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 patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11182M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	0	0.00	*2242.92	^a Stelara [JC]	^a Steqeyma [EW]
					^a Wezlana [AN]	

VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they

have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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

Severe Crohn disease

Treatment Phase: Initial 4 (additional dose at week 10)

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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

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.

vedolizumab 300 mg injection, 1 vial

14630B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	2802.43	Entyvio [TK]

VEDOLIZUMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent 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) 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 Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Special Pricing Arrangements apply.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

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 not have achieved an adequate response to 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 not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to 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 not achieving 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 not achieving 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 not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and
- (c) if applicable, details of intestinal inflammation marker/s; and
- (d) if applicable, the CDAI score and the date of assessment; and
- (e) the date of the most recent clinical assessment.

Evidence of not achieving 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.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, the CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) 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; and
- (c) if applicable, the date of the most recent clinical assessment; and
- (d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility

requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy 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 while off treatment with targeted therapy; **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; and evidence of flared disease while off treatment with targeted therapy; **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 evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease 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.

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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted 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.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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 Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **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.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and
- (b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and
- (c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **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; **OR**

- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 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) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as 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 targeted therapy 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.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 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 through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient 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 or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

vedolizumab 300 mg injection, 1 vial

10390W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	0	0.00	2802.43	Entyvio [TK]

■ ZILUCOPLAN

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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- azathioprine,
- ciclosporin,
- cyclophosphamide,
- methotrexate,
- mycophenolate
- tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOtpxZ-3w%3D%3D>

The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialed a different gMG biologic, but did not respond to treatment; or
 - b) the continuing restriction if they have trialed a different gMG biological agent and have responded to treatment.
- Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

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

- (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).

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15276B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	21395.05	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15303K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	29521.05	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15287N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	0.00	41658.62	Zilbrysq [UC]

■ ZILUCOPLAN

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 Definitions for the purposes of administering this restriction.

Where the term '**gMG biological agent**' is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

- (i) azathioprine,
- (ii) ciclosporin,
- (iii) cyclophosphamide,
- (iv) methotrexate,
- (v) mycophenolate
- (vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf>

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at <https://www.criteria.blood.gov.au/NeurologicalScales#MGC>

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at <https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttxpZ-3w%3D%3D>

: The following are settings and time limits where a gMG biological agent are PBS subsidised:

- (1) Three months of acute treatment - 'acute severe gMG'.
- (2) Six months of bridging therapy - 'bridging therapy for gMG'.
- (3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

- a) the initial restriction if they have trialed a different gMG biologic, but did not respond to treatment; or
- b) the continuing restriction if they have trialed a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, 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

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

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

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

- (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).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

-
- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it 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).

Authority Required

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

- (a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

- (b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);
- (c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it 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).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

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.

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15316D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	21395.05	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15286M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	29521.05	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15325N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	0.00	41658.62	Zilbrysq [UC]

Botulinum Toxin Program

▪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)

18907

Severe primary axillary hyperhidrosis

Clinical criteria:

- Patient must have previously failed topical aluminium chloride after one to two months of treatment; **OR**
- Patient must be intolerant to topical aluminium chloride 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.

Clinical criteria:

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

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	0	0.00	*1099.24	25.00	Botox [VE]

Growth Hormone Program

▪SOMAPACITAN

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An appropriate amount of drug (maximum quantity in units) for this treatment phase listing per prescription, where only one of the two strengths is prescribed at any given time, is outlined below:

10 mg strength presentation:

Below 13 kg: up to 3 units

13 to 16 kg: up to 4 units

16 to 21 kg: up to 5 units

21 to 25 kg: up to 8 units

15 mg strength presentation:

Below 19 kg: up to 3 units

19 to 24 kg: up to 4 units

24 to 32 kg: up to 5 units

32 to 47 kg: up to 8 units

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 1st percentile for age and sex; **OR**
- Patient must have a current height above the 1st and at or below the 25th percentiles 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 1st and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 1st percentile for age and sex, **AND**
- Patient must have 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 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 1st adult height percentile.

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

- (i) details of the proposed prescription; 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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.

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) details of the proposed prescription; 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.

somapacitan 10 mg/1.5 mL injection, 1.5 mL pen device

15384Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	1	0.00	*3770.84	25.00	Sogroya [NO]

somapacitan 15 mg/1.5 mL injection, 1.5 mL pen device

15374E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	1	0.00	*5631.64	25.00	Sogroya [NO]

■ SOMAPACITAN

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

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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An appropriate amount of drug (maximum quantity in units) for this treatment phase listing per prescription, where only one of the two strengths is prescribed at any given time, is outlined below:

10 mg strength presentation:

Below 10 kg: up to 2 units

10 to 16 kg: up to 3 units

16 to 21 kg: up to 4 units

21 to 25 kg: up to 6 units

15 mg strength presentation:

Below 16 kg: up to 2 units

16 to 24 kg: up to 3 units

24 to 32 kg: up to 4 units

32 to 47 kg: up to 6 units

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 50th 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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 1st 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) details of the proposed prescription; 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.

somapatitan 10 mg/1.5 mL injection, 1.5 mL pen device

15385R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	1	0.00	*2840.46	25.00	Sogroya [NO]

somapatitan 15 mg/1.5 mL injection, 1.5 mL pen device

15367T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	1	0.00	*4236.06	25.00	Sogroya [NO]

■ 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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

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 1st percentile for age and sex; **OR**
- Patient must have a current height above the 1st and at or below the 25th percentiles 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 1st and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**

- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 1st percentile for age and sex, **AND**
- Patient must have 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 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 1st adult height percentile.

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

- (i) details of the proposed prescription; 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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.

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) details of the proposed prescription; 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 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	0.00	384.16	25.00	Ngenla [PF]

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	0.00	946.54	25.00	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

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see 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

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 50th 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 1st 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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) details of the proposed prescription; 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 1st percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25th 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 1st 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) details of the proposed prescription; 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 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	0.00	384.16	25.00	Ngenla [PF]

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	0.00	946.54	25.00	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**
- 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 made in writing and must include:

1. Details of the proposed prescription, specifying the active ingredient name, form and strength of the medicine, followed by the brand name; 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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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) 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 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 made in writing and must include:

1. Details of the proposed prescription, specifying the active ingredient name, form and strength of the medicine, followed by the brand name; **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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 made in writing and must include:

1. Details of the proposed prescription, specifying the active ingredient name, form and strength of the medicine, followed by the brand name; **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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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	0.00	166.81	25.00	Genotropin GoQuick [PF]

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	0.00	166.81	25.00	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	0.00	198.32	25.00	Saizen [SG]

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	0.00	387.40	25.00	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	0.00	387.40	25.00	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

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

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 1st percentile for age and sex, **AND**
- Patient must have 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 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 2025* 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. Details of the proposed prescription; **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 1st 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 1st percentile for age and sex; **OR**
- Patient must have a current height above the 1st and at or below the 25th percentiles 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 1st and at or below the 25th 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 2025* 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. Details of the proposed prescription; 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. 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 1st percentile for age and sex; **OR**
- Patient must have a current height above the 1st 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 1st 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 2025* 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. Details of the proposed prescription; 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 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.

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 2025* 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. Details of the proposed prescription; 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 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

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 IGF-1 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 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 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 2025* 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. Details of the proposed prescription; **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 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 155.0 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 2025* 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. Details of the proposed prescription; 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 1st percentile for age and sex, **AND**
- Patient must have 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 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 2025* 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. Details of the proposed prescription; 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/1.73m² 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/1.73m² 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 1st percentile for age and sex; **OR**
- Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to 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 1st and at or below the 25th 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 2025* 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. Details of the proposed prescription; **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. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m² ; **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 15 mg/1.5 mL injection, 1.5 mL cartridge

15394F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	497.08	25.00	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

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

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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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

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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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

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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; 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 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/1.73m², **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 2025* 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. Details of the proposed prescription; **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/1.73m²; **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/1.73m² 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/1.73m² 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 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: (i) a height no higher than the 1st 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 2025* 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. Details of the proposed prescription; **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/1.73m² 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 2025* 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. Details of the proposed prescription; **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 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 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 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 2025* 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. Details of the proposed prescription; 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had 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 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 2025* 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. Details of the proposed prescription; 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 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to 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 and at or below the 25th 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 1st and at or below the 25th 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/1.73m² 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/1.73m² 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 2025* 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. Details of the proposed prescription; **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/1.73m²; **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/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

15399L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	497.08	25.00	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
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

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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; 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.

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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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 2025* 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. Details of the proposed prescription; 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 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for the 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/m²/week or greater for 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/1.73m², **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 2025* 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. Details of the proposed prescription; **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.

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/1.73m² 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/1.73m² 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 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: (i) a height no higher than the 1st 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 2025* 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. Details of the proposed prescription; **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/1.73m² 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles 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 and at or below the 25th 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 1st and at or below the 25th 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 2025* 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. Details of the proposed prescription; 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 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. 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st 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 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 2025* 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. Details of the proposed prescription; **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 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. 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/m²/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 7.5mg/m²/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 7.5mg/m²/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 7.5mg/m²/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 7.5mg/m²/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 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 2025* 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. Details of the proposed prescription; 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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 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 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 2025* 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. Details of the proposed prescription; **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/m²/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/m²/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/m²/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/m²/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/m²/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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had 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 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 2025* 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. Details of the proposed prescription; **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/m²/week or greater for the 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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment; **OR**
- Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to 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 and at or below the 25th 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 1st and at or below the 25th 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/1.73m² 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/1.73m² 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 2025* 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. Details of the proposed prescription; **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 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/1.73m²; **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/1.73m² 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 50th 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) details of the proposed prescription; 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 50th 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) details of the proposed prescription; 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 15 mg/1.5 mL injection, 1.5 mL cartridge

15417K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	0.00	497.08	25.00	SciTropin A [SA]

Repatriation Pharmaceutical Benefits

▪ DRESSING HYDROFIBRE WITH SILVER

Authority Required

Wounds

Clinical criteria:

- Patient must have a wound where there is evidence of critical colonisation; **OR**
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings hydrofibre with silver 2 cm x 45 cm ribbon, 5

15409B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	0	0.00	213.09	7.70	Aquacel Ag+ Ribbon 413571 [CC]

dressings hydrofibre with silver 10 cm x 10 cm dressing, 10

15373D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	0	0.00	251.41	7.70	Aquacel Ag+ Extra 413567 [CC]

dressings hydrofibre with silver 15 cm x 15 cm dressing, 5

15396H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	0	0.00	268.78	7.70	Aquacel Ag+ Extra 413568 [CC]

▪ MAGNESIUM

Restricted benefit

Hypomagnesaemia

The condition must be documented in the patient's medical records.

Magnesium 37.4 mg tablet, 120

15372C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	0	0.00	27.68	7.70	A-WON Magnesium [WN]

▪ PANTHENOL

Note To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

panthenol conditioner, 250 g

15408Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	0.00	23.52	7.70	SebiRinse [EO]