



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Section 100 – Items Available under Special Arrangement - Volume 2

Effective 1 February 2022

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

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Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 February 2022 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.78
	Dangerous drug fee	\$4.82
	Extemporaneously-prepared	\$9.82
	Allowable additional patient charge*	\$4.54
Additional Fees (for safety net prices):	Ready-prepared	\$1.30
	Extemporaneously-prepared	\$1.67
Patient Co-payments:	General	\$42.50
	Concessional	\$6.80
Safety Net Thresholds:	General	\$1542.10
	Concessional	\$326.40
Safety Net Card Issue Fee:		\$10.65

* 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 February 2022. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Deletions

Deletion – Item

12616B **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules (*ADRENALINE RENAUDIN*)

General Pharmaceutical Benefits

Additions

Addition – Item

12826C **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
12830G **LEVOTHYROXINE**, levothyroxine sodium 125 microgram tablet, 200 (*Eltroxin*)
12828E **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12831H **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12835M **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12827D **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)
12829F **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)
12836N **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)

Addition – Brand

1354G *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
1354G *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
2478K *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
2478K *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
9125G *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
9125G *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
1381Q *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
1381Q *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
2482P *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
2482P *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
9126H *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
9126H *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
1415L *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 70 mg tablet, 60
1415L *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 70 mg tablet, 60
2485T *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 70 mg tablet, 60
2485T *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 70 mg tablet, 60

9127J	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 70 mg tablet, 60
9127J	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 70 mg tablet, 60
1416M	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
1416M	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
9342Q	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
9342Q	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
9343R	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
9343R	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
2896K	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2943X	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2966D	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56
8700X	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
9432K	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
8701Y	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
9433L	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
11408K	<i>Ezetimibe GH, GQ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
11408K	<i>Ezetimibe Sandoz, SZ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
9483D	<i>EZEVYT 10/10, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9484E	<i>EZEVYT 10/20, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
8881K	<i>EZEVYT 10/40, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8882L	<i>EZEVYT 10/80, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
1433K	<i>FLUDROCORTISONE MEDSURGE, DZ</i> – FLUDROCORTISONE ACETATE , fludrocortisone acetate 100 microgram tablet, 100
12300J	<i>FULVESTRANT EVER PHARMA, IT</i> – FULVESTRANT , fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes
10416F	<i>GLATIRAMER ACETATE-TEVA, EV</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
10416F	<i>Glatira, JU</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
11625W	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
11634H	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
11643T	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
12709X	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 100 mg capsule, 60
12722N	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 100 mg capsule, 60
12723P	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 400 mg capsule, 30
12754G	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 400 mg capsule, 30
2174K	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
2174K	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
9287T	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
9287T	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
2175L	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
2175L	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
2173J	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
2173J	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
1824B	<i>FEMIN, LI</i> – MEFENAMIC ACID , mefenamic acid 250 mg capsule, 50
9353G	<i>Mesalazine 1.2 TAKEDA, NQ</i> – MESALAZINE , mesalazine 1.2 g modified release tablet, 60
2387P	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 18 mg modified

	release tablet, 30
2172H	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 27 mg modified release tablet, 30
2388Q	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 36 mg modified release tablet, 30
2432B	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 54 mg modified release tablet, 30
8513C	<i>NOUMED MIRTAZAPINE, VO</i> – MIRTAZAPINE , mirtazapine 30 mg tablet, 30
8883M	<i>NOUMED MIRTAZAPINE, VO</i> – MIRTAZAPINE , mirtazapine 45 mg tablet, 30
1692C	<i>Nitrofurantoin BNM, BZ</i> – NITROFURANTOIN , nitrofurantoin 50 mg capsule, 30
1693D	<i>Nitrofurantoin BNM, BZ</i> – NITROFURANTOIN , nitrofurantoin 100 mg capsule, 30
12023T	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
12048D	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
2622B	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
5195K	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
8355R	<i>NOUMED TELMISARTAN, VO</i> – TELMISARTAN , telmisartan 40 mg tablet, 28
8356T	<i>NOUMED TELMISARTAN, VO</i> – TELMISARTAN , telmisartan 80 mg tablet, 28
8163P	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 25 mg tablet, 60
8164Q	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 50 mg tablet, 60
8165R	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 100 mg tablet, 60
8166T	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 200 mg tablet, 60

Addition – Equivalence Indicator

2896K	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2943X	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2966D	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56
1433K	<i>Florinef, AS</i> – FLUDROCORTISONE ACETATE , fludrocortisone acetate 100 microgram tablet, 100
10416F	<i>Copaxone, TB</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
1824B	<i>Ponstan, PF</i> – MEFENAMIC ACID , mefenamic acid 250 mg capsule, 50
9353G	<i>Mezavant, TK</i> – MESALAZINE , mesalazine 1.2 g modified release tablet, 60

Addition – Note

11419B	IBRUTINIB , ibrutinib 140 mg capsule, 120 (<i>Imbruvica</i>)
2174K	LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
9287T	LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
2175L	LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
2173J	LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)

Deletions

Deletion – Item

12617C	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules (<i>ADRENALINE RENAUDIN</i>)
12618D	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules (<i>ADRENALINE RENAUDIN</i>)
10647J	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10673R	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10665H	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)
10666J	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)

Deletion – Brand

8358X	<i>Clopidogrel Sandoz, SZ</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
9317J	<i>Clopidogrel Sandoz, SZ</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
11815W	<i>Semglee, AF</i> – INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices
1558B	<i>Isomonit, SZ</i> – ISOSORBIDE MONONITRATE , isosorbide mononitrate 60 mg modified release tablet, 30
1906H	<i>Adefin XL 30, AF</i> – NIFEDIPINE , nifedipine 30 mg modified release tablet, 30
1907J	<i>Adefin XL 60, AF</i> – NIFEDIPINE , nifedipine 60 mg modified release tablet, 30
1898X	<i>Feldene, PF</i> – PIROXICAM , piroxicam 20 mg capsule, 25
5204X	<i>Feldene, PF</i> – PIROXICAM , piroxicam 20 mg capsule, 25
1978D	<i>Rani 2, AF</i> – RANITIDINE , ranitidine 150 mg tablet, 60
1977C	<i>Rani 2, AF</i> – RANITIDINE , ranitidine 300 mg tablet, 30

Deletion – Equivalence Indicator

1016L	<i>Link Medical Products Pty Ltd, LM</i> – ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules
5004J	<i>Link Medical Products Pty Ltd, LM</i> – ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules
11815W	<i>Optisulin SoloStar, WA</i> – INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices

Deletion – Note

2896K	DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
2943X	DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
2966D	DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
11815W	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices (<i>Optisulin SoloStar,)</i>
9039R	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL cartridges (<i>Optisulin</i>)

Deletion – Note

11815W	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices (<i>Optisulin SoloStar,)</i>
9039R	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL cartridges (<i>Optisulin</i>)

Alterations**Alteration – Brand Name**

From	
12683M	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
To	
12683M	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
From	
12704P	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
To	
12704P	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
From	
12725R	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
To	
12725R	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
From	
12755H	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
To	
12755H	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial

Alteration – Restriction

12291X	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12292Y	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
11419B	IBRUTINIB , ibrutinib 140 mg capsule, 120 (<i>Imbruvica</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
2923W	Rythmodan – DISOPYRAMIDE , disopyramide 100 mg capsule, 100	SW	PB
11677N	Acimax Tablets – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
12270T	Acimax Tablets – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
9109K	Acimax Tablets – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
9110L	Acimax Tablets – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ

Advance Notices

1 March 2022

Deletion – Brand

12336G	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 4 x 0.4 mL pen devices
12343P	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12344Q	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12346T	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12392F	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12404W	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12418N	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 4 x 0.4 mL pen devices
12427C	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12441T	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12445B	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12452J	Humira, VE – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
8295N	Candesartan Aspen 4, RW – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8296P	Candesartan Aspen 8, RW – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8297Q	Candesartan Aspen 16, RW – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8889W	Candesartan Aspen 32, RW – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
8504N	Candesartan Combi Aspen 16/12.5, RW – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	Candesartan Combi Aspen 32/12.5, RW – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G	Candesartan Combi Aspen 32/25, RW – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
1759N	DBL Cefotaxime, PF – CEFOTAXIME , cefotaxime 2 g injection, 10 vials
1769D	DBL Cefotaxime, PF – CEFOTAXIME , cefotaxime 2 g injection, 10 vials
1834M	Gabapentin Aspen 300, RW – GABAPENTIN , gabapentin 300 mg capsule, 100
1835N	Gabapentin Aspen 400, RW – GABAPENTIN , gabapentin 400 mg capsule, 100
8389M	Gabapentin Aspen 800, RW – GABAPENTIN , gabapentin 800 mg tablet, 100
8505P	Gabapentin Aspen 100, RW – GABAPENTIN , gabapentin 100 mg capsule, 100
8559L	Gabapentin Aspen 600, RW – GABAPENTIN , gabapentin 600 mg tablet, 100
2848X	Lamotrigine Aspen 25, RW – LAMOTRIGINE , lamotrigine 25 mg tablet, 56
2849Y	Lamotrigine Aspen 50, RW – LAMOTRIGINE , lamotrigine 50 mg tablet, 56
2850B	Lamotrigine Aspen 100, RW – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	Lamotrigine Aspen 200, RW – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8063J	Lamotrigine Aspen 5, RW – LAMOTRIGINE , lamotrigine 5 mg tablet, 56
11508Q	Methoblastin PFS, PF – METHOTREXATE , methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes
11509R	Methoblastin PFS, PF – METHOTREXATE , methotrexate 20 mg/0.8 mL injection, 4 x 0.8 mL syringes
11525N	Methoblastin PFS, PF – METHOTREXATE , methotrexate 7.5 mg/0.3 mL injection, 4 x 0.3 mL syringes
11526P	Methoblastin PFS, PF – METHOTREXATE , methotrexate 10 mg/0.4 mL injection, 4 x 0.4 mL syringes

11544N	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 25 mg/mL injection, 4 x 1 mL syringes
2774B	<i>Brevinor, PF</i> – NORETHISTERONE + ETHINYLESTRADIOL , norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28
5442K	<i>TOBRAMYCIN WOCKHARDT, WC</i> – TOBRAMYCIN , tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

1 April 2022

Deletion – Brand

8748K	<i>Edecrin, FK</i> – ETACRYNIC ACID , etacrynic acid 25 mg tablet, 100
8450R	<i>Dimirel, AV</i> – GLIMEPIRIDE , glimepiride 1 mg tablet, 30
1621H	<i>Metronide 400, AV</i> – METRONIDAZOLE , metronidazole 400 mg tablet, 21
5155H	<i>Metronide 400, AV</i> – METRONIDAZOLE , metronidazole 400 mg tablet, 21

1 May 2022

Deletion – Brand

1324Q	<i>Lopresor 50, NV</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 50 mg, 100
1325R	<i>Lopresor 100, NV</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 100 mg, 60

Highly Specialised Drugs Program (Private Hospital)

Deletions

Deletion – Item

10623D	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10635R	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10637W	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)
10675W	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)

Deletion – Brand

12784W	<i>Celazadine, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6100C	<i>Celazadine, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	<i>Celazadine, CJ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
12139X	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 62.5 mg tablet, 60
12143D	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 62.5 mg tablet, 60
12148J	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 62.5 mg tablet, 60
6429J	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 62.5 mg tablet, 60
12146G	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 125 mg tablet, 60
6430K	<i>Bosentan Sandoz, SZ</i> – BOSENTAN , bosentan 125 mg tablet, 60
6363X	<i>Fulphila, AF</i> – PEGFILGRASTIM , pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

6363X	PEGFILGRASTIM , pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Neulasta, Pelgraz, Ristempa, Tezmota, Ziextenzo</i>)

Alteration – Manufacturer Code

6249X	<i>Caelyx</i> – DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) , doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial	From JC	To BX

Highly Specialised Drugs Program (Public Hospital)

Deletions

Deletion – Item

10646H	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)

10678B **RIBAVIRIN**, ribavirin 400 mg tablet, 28 (*Ibavyr*)
 10638X **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)
 10663F **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)

Deletion – Brand

12771E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 9597D *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 9598E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 12134P *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12140Y *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12145F *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 5618Q *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12149K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
 5619R *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
 9514R *Fulphila, AF* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

9514R **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta, Pelgraz, Ristempa, Tezmota, Ziextenzo*)

Alteration – Manufacturer Code

5705G	<i>Caelyx</i> – DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) , doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial	From JC	To BX

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

11657M **ATAZANAVIR**, atazanavir 300 mg capsule, 60 (*Atazanavir Mylan*)

Deletion – Brand

10349Q *Atazanavir Mylan, AF* – **ATAZANAVIR**, atazanavir 200 mg capsule, 60

Deletion – Equivalence Indicator

10349Q *Reyataz, BQ* – **ATAZANAVIR**, atazanavir 200 mg capsule, 60
 10321F *Reyataz, BQ* – **ATAZANAVIR**, atazanavir 300 mg capsule, 30

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

12832J **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 10 cm x 13 cm dressing, 50 (*Mesorb 677001*)
 12825B **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 10 cm x 23 cm dressing, 50 (*Mesorb 677401*)
 12837P **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610000*)
 12834L **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610300*)
 12833K **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610500*)
 12824Y **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 23 cm x 25 cm dressing, 30 (*Mesorb 677701*)

Deletions

Deletion – Item

12798N	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 10 cm x 13 cm dressing, 50 (<i>Mesorb 677001</i>)
12793H	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 10 cm x 23 cm dressing, 50 (<i>Mesorb 677401</i>)
12807C	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 12.5 cm x 12.5 cm dressing, 10 (<i>Mextra Superabsorbent 610000</i>)
12788C	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 17.5 cm x 22.5 cm dressing, 10 (<i>Mextra Superabsorbent 610300</i>)
12783T	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 22.5 cm x 32.5 cm dressing, 10 (<i>Mextra Superabsorbent 610500</i>)
12781Q	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 23 cm x 25 cm dressing, 30 (<i>Mesorb 677701</i>)

Deletion – Brand

10598T	<i>Parapane Osteo, AF</i> – PARACETAMOL , paracetamol 665 mg modified release tablet, 96

Advance Notices

1 March 2022

Deletion – Brand

4591P	<i>Gabapentin Aspen 100, RW</i> – GABAPENTIN , gabapentin 100 mg capsule, 100
4592Q	<i>Gabapentin Aspen 300, RW</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
4593R	<i>Gabapentin Aspen 400, RW</i> – GABAPENTIN , gabapentin 400 mg capsule, 100
4594T	<i>Gabapentin Aspen 600, RW</i> – GABAPENTIN , gabapentin 600 mg tablet, 100
4595W	<i>Gabapentin Aspen 800, RW</i> – GABAPENTIN , gabapentin 800 mg tablet, 100

About the Schedule

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

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

For detailed information about the prescribing and supply of pharmaceutical benefits go to www.pbs.gov.au

For information about the operational aspects of the PBS, such as, PBS claiming, authority applications and stationery supplies contact the Department of Human Services at www.humanservices.gov.au

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

Symbols and Abbreviations Used in the Schedule

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

Restricted Benefits

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

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

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

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

Guidelines and General Statements

General Statement for Drugs for the Treatment of Hepatitis C

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

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

Treatment criteria:

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

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

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

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

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

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

HEPATITIS C – NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
All genotypes (Pan-genotypic regimens)	SOFOBUVIR + VELPATASVIR [12 weeks] OR GLECAPREVIR + PIBRENTASVIR [8 weeks]	SOFOBUVIR + VELPATASVIR [12 weeks] OR SOFOBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ³ OR GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] ²
Genotype 1	LEDIPASVIR + SOFOBUVIR [8 or 12 weeks] ¹	LEDIPASVIR + SOFOBUVIR [12 weeks]
Genotype 2	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 3	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 4	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 5 & 6	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.

KEY

RBV - ribavirin

HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
All genotypes (Pan-genotypic regimens)	SOFOSBUVIR + VELPATASVIR [12 weeks] ^{4,6} OR GLECAPREVIR + PIBRENTASVIR [8 weeks] ⁷	SOFOSBUVIR + VELPATASVIR [12 weeks] ^{4,6} OR SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] ³ OR GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] ⁵
Genotype 1	LEDIPASVIR + SOFOSBUVIR [12 weeks]	LEDIPASVIR + SOFOSBUVIR [24 weeks]
Genotype 2	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 3	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 4	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.
Genotype 5 & 6	Refer to treatment naïve pan-genotypic regimens above.	Refer to treatment experienced pan-genotypic regimens above.

KEY

RBV – ribavirin

- ¹ LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks] for treatment-naïve, non-cirrhotic patients:
 - consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
 - otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.
- ² GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:
 - treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
 - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
 - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
 - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
- ³ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.
- ⁴ SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
- ⁵ GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:
 - treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
 - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
 - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
 - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
- ⁶ SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.
- ⁷ GLECAPREVIR + PIBRENTASVIR – A treatment duration of 12 weeks may be considered for patients with compensated cirrhosis, at the discretion of the prescriber.

Pharmaceutical Benefits Schedules

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ALIMENTARY TRACT AND METABOLISM

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Various alimentary tract and metabolism products

■ TEDUGLUTIDE

Note Special Pricing Arrangements apply.

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

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

Treatment criteria:

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

Clinical criteria:

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

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

11812Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	21887.78	Revestive [TK]

■ TEDUGLUTIDE

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
 - Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
 - Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks, **AND**
 - Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
 - The treatment must not exceed 12 months under this restriction, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition.
- Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:
- for a patient of any age, the mean number of days of parenteral support per week
 - for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.
- Determine the mean over the four weeks immediately prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i). Assessment of treatment response/non-response in the 'First continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.
- A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.
- The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

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

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

11795T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	21887.78	Revestive [TK]

▪ TEDUGLUTIDE

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Type III Short bowel syndrome with intestinal failure

Treatment Phase: First continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; OR
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline.

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

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

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

From 1 September 2021

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

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

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

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

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

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

- a completed authority prescription form(s); 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).

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

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received PBS-subsidised first-continuing treatment with this drug for this condition and achieved a treatment response in the preceding treatment period; OR
- Patient must have received PBS-subsidised commencement of treatment following a trial cessation period and not have previously experienced a failure to respond to treatment with this drug for this condition.

Treatment response**Adult:**

In a subsequent continuing treatment application, treatment response in a patient aged at least 18 years is one of:

- (i) a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment for PBS-subsidised treatment; or
- (ii) parenteral support completely ceasing (due to clinical benefit from this drug) for a period of at least 4 consecutive weeks

Child (yet to turn 18 years of age):

In a subsequent continuing treatment application, treatment response in a child is one of:

- (iii) a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment for PBS-subsidised treatment; or
- (iv) a reduction in the mean weekly volume of parenteral support (mL per kg of body weight) of at least 20% since the last assessment for PBS-subsidised treatment; or
- (v) parenteral support completely ceasing (due to clinical benefit from this drug) for a period of at least 4 consecutive weeks.

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

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

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

Treatment failure**Adult:**

In a subsequent continuing treatment application, treatment failure is defined as an increase in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to the most recent authority application.

Child (yet to turn 18 years of age):

In a subsequent continuing treatment application, treatment failure is defined as at least one of the following occurring:

- (i) an increase in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to the most recent authority application; or
- (ii) an increase of 20% or more in the mean weekly volume of parenteral support (mL per kg of body weight; parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to most recent authority application.

Patients who experience failure of treatment must permanently discontinue treatment.

Treatment stability

A patient who neither demonstrates a treatment response as defined above nor a treatment failure as defined above since the last assessment for PBS-subsidised treatment is considered to have 'treatment stability'.

Trial cessation period

A patient with treatment stability must undertake a trial cessation period. A patient who re-commences treatment after a trial cessation period is exempt from further trial cessation periods.

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

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

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Recommencement of treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have undertaken a trial cessation period due to experiencing a stable parenteral support regimen in the first continuing or subsequent continuing treatment phase, and not due to a treatment failure; OR
- Patient must have undertaken a trial cessation period for any medical reason other than lack of treatment efficacy, **AND**
- Patient must have experienced deterioration during a trial cessation period.

Deterioration during the trial cessation period includes an increase in parenteral support use, as well as changes in renal function, urinary sodium levels and changes in body weight in the absence of an increase in parenteral support use. This is not an exhaustive list of the signs/symptoms of disease deterioration - the treating physician must be satisfied that in the absence of treatment with this drug, the patient's condition has deteriorated.

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

- (a) a completed authority prescription form(s); and

BLOOD AND BLOOD FORMING ORGANS

(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).

Note Authority applications to continue treatment after this application should occur under the 'Subsequent continuing treatment' phase.

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

11806J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21887.78	Revestive [TK]

■ BLOOD AND BLOOD FORMING ORGANS

■ ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

■ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

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

Applications for 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 thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

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

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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

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

Applications for 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 thrombocytopenia

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

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with romiplostim for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
- (3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

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

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than 4 weeks old at the time of application.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note 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. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note 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. EST Monday to Friday).

eltrombopag 25 mg tablet, 28

5827Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1340.54	Revolade [NV]

eltrombopag 50 mg tablet, 28

5828R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2633.30	Revolade [NV]

▪ ROMIPLOSTIM**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

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

Applications for 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 thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**

- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

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

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

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

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

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

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

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

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

Applications for 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 thrombocytopenia

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

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with eltrombopag for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

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

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

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
- (3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

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

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

Applications for 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 thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L
OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than 4 weeks old at the time of application.

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

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

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note 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. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from eltrombopag to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

BLOOD AND BLOOD FORMING ORGANS

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note 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. EST Monday to Friday).

romiplostim 250 microgram injection, 1 vial

9697J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	521.66	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9699L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1035.55	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

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

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

6323T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*899.00	Aranesp [AN]

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

6493R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*3052.42	Aranesp SureClick [AN]

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

6491P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1685.38	Aranesp SureClick [AN]

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

6326Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2064.34	Aranesp [AN]

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

6321Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*544.46	Aranesp [AN]

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

6490N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1291.86	Aranesp SureClick [AN]

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

6492Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2064.26	Aranesp SureClick [AN]

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

6320P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*292.76	Aranesp [AN]

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

6325X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1291.84	Aranesp [AN]

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

6322R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*742.02	Aranesp [AN]

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

6324W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1107.24	Aranesp [AN]

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

6438W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1685.32	Aranesp [AN]

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

6488L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*544.50	Aranesp SureClick [AN]

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

6489M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*898.90	Aranesp SureClick [AN]

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

6365B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3052.40	Aranesp [AN]

■ EPOETIN ALFA**Authority required (STREAMLINED)****9688**

Anaemia associated with intrinsic renal disease

Clinical criteria:

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

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

6206P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*687.48	Eprex 4000 [JC]

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

6251B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*231.30	Eprex 1000 [JC]

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

6204M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*421.38	Eprex 2000 [JC]

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

6302Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*853.98	Eprex 5000 [JC]

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

6207Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1563.96	Eprex 10000 [JC]

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

6339P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1011.36	Eprex 40,000 [JC]

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

6205N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*541.50	Eprex 3000 [JC]

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

6305W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1300.50	Eprex 8000 [JC]

BLOOD AND BLOOD FORMING ORGANS

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

6434P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3030.46	Eprex 20,000 [JC]

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

6303R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1012.28	Eprex 6000 [JC]

▪ EPOETIN BETA

Authority required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

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

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

6482E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*723.26	NeoRecormon [RO]

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

6484G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1064.48	NeoRecormon [RO]

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

6483F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*898.54	NeoRecormon [RO]

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

6481D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*569.60	NeoRecormon [RO]

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

6485H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1643.76	NeoRecormon [RO]

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

6480C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*443.14	NeoRecormon [RO]

▪ EPOETIN LAMBDA

Authority required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

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

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

9688X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*723.24	Novicrit [SZ]

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

9685R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*243.06	Novicrit [SZ]

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

9593X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1366.38	Novicrit [SZ]

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

9588P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*898.50	Novicrit [SZ]

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

9590R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1064.44	Novicrit [SZ]

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

9595B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1643.74	Novicrit [SZ]

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

9687W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*569.58	Novicrit [SZ]

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

9686T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*443.12	Novicrit [SZ]

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

Anaemia associated with intrinsic renal disease

Clinical criteria:

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

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

9579E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1606.50	Mircera [RO]

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

9580F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2742.36	Mircera [RO]

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

9577C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*984.00	Mircera [RO]

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

9576B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*762.62	Mircera [RO]

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

9575Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*526.14	Mircera [RO]

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

9574X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*318.80	Mircera [RO]

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

9578D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1134.54	Mircera [RO]

■ CARDIOVASCULAR SYSTEM**■ ANTIHYPERTENSIVES****OTHER ANTIHYPERTENSIVES***Antihypertensives for pulmonary arterial hypertension***■ AMBRISENTAN**

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

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

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- a completed authority prescription form; and
- a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

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

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

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

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

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

Treatment criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

ambrisentan 10 mg tablet, 30

9649W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.32	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

9648T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.32	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^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.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

Treatment criteria:

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

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

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.
- For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. 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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.
- For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil
- 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.
- 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.
- For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil
- 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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

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. EST Monday to Friday).

ambrisentan 10 mg tablet, 30

12180C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.32	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

12201E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1892.32	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

BOSENTAN

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

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

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

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.
- The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

bosentan 62.5 mg tablet, 60

12143D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

▪ **BOSENTAN**

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

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

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

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

Note 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 dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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.

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	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

▪ **BOSENTAN**

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

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

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
 - The treatment must be the sole PBS-subsidised PAH agent for this condition.
- The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

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

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

Treatment criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

bosentan 125 mg tablet, 60

6430K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a Tracleer [JC]

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	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

▪ **BOSENTAN**

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

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

Treatment criteria:

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

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

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

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.

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. EST Monday to Friday).

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	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

▪ **BOSENTAN**

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

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

Treatment criteria:

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

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

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

bosentan 125 mg tablet, 60

12146G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	455.64	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a Tracleer [JC]

▪ **EPOPROSTENOL**

Note Pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial & diluent and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

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

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

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

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

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

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'.

epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack

11069N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*933.58	^a Flolan [GK]

epoprostenol 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	30	5	..	*1046.08	^a EPOPROSTENOL SUN [RA]	^a Veletri [JC]

■ EPOPROSTENOL

Note Pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial & diluent and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

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

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

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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'.

epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	30	5	..	*1827.58	^a EPOPROSTENOL SUN [RA]	^a Veletri [JC]

epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack

11082G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*1827.58	^a Flolan [GK]

■ **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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. 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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; **OR**
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; **OR**
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

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

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

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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'.

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	..	371.35	Ventavis [BN]

■ MACITENTAN

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

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

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

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

Treatment criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

macitentan 10 mg tablet, 30

10134J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2780.43	Opsumit [JC]

■ **MACITENTAN**

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

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

Treatment criteria:

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

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

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

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. EST Monday to Friday).

macitentan 10 mg tablet, 30

12135Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2780.43	Opsumit [JC]

■ RIOCIQUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

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

Applications for 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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**

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

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

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

Applications for 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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

CARDIOVASCULAR SYSTEM

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

riociguat 2 mg tablet, 84

11017W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3483.20	Adempas [BN]

riociguat 1.5 mg tablet, 42

10974N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 500 microgram tablet, 84

11008J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3483.20	Adempas [BN]

riociguat 2 mg tablet, 42

11012N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 500 microgram tablet, 42

11009K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 2.5 mg tablet, 42

10985E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 1 mg tablet, 42

10990K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 2.5 mg tablet, 84

11018X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3483.20	Adempas [BN]

riociguat 1.5 mg tablet, 84

10975P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3483.20	Adempas [BN]

riociguat 1 mg tablet, 84

11010L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3483.20	Adempas [BN]

■ RIOCIQUAT

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 number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

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

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

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

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

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

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

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

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

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

Authority required

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

riociguat 500 microgram tablet, 42

11031N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 1 mg tablet, 42

11028K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

▪ RIOCIQUAT

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

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

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

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

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

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

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

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

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

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

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

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

Authority required

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

riociguat 2 mg tablet, 84

11030M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3483.20	Adempas [BN]

riociguat 1.5 mg tablet, 42

11046J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 500 microgram tablet, 84

11058B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3483.20	Adempas [BN]

riociguat 2 mg tablet, 42

11045H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 2.5 mg tablet, 42

11052Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1765.49	Adempas [BN]

riociguat 2.5 mg tablet, 84

11035T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3483.20	Adempas [BN]

riociguat 1.5 mg tablet, 84

11061E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3483.20	Adempas [BN]

riociguat 1 mg tablet, 84

11060D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3483.20	Adempas [BN]

SELEXIPAG

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

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

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

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

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

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

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

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

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

selexipag 800 microgram tablet, 60

12253X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3497.78	Upravi [JC]

SELEXIPAG

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**

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

Treatment criteria:

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

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

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

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

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

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

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

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

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

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

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

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

(i) Hospitalisation due to worsening PAH;

(ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;

(iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;

(iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;

(v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

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

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

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

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

Note 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.

selexipag 200 microgram tablet, 140

12241G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8097.78	Upravi [JC]

SELEXIPAG

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

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

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

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

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

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

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

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

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR

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

Treatment criteria:

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

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

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

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

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

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

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

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

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

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

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

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

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH

- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

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.

selexipag 1.4 mg tablet, 60

12251T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 400 microgram tablet, 60

12260G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 1.6 mg tablet, 60

12264L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12257D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 1 mg tablet, 60

12245L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 600 microgram tablet, 60

12248P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 800 microgram tablet, 60

12246M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

selexipag 200 microgram tablet, 60

12242H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3497.78	Uptravi [JC]

■ **SILDENAFIL**

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

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

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

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

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

Treatment criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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	..	183.90	^a APO-Sildenafil PHT [TX] ^a SILDATIO PHT [RW] ^a Sildenafil PHT APOTEX [TY]	^a Revatio [UJ] ^a Sildenafil AN PHT 20 [EA] ^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.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **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.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **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.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**

- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.

Treatment criteria:

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

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

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

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

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

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. EST Monday to Friday).

sildenafil 20 mg tablet, 90

12138W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	183.90	^a APO-Sildenafil PHT [TX] ^a SILDATIO PHT [RW] ^a Sildenafil PHT APOTEX [TY]	^a Revatio [UJ] ^a Sildenafil AN PHT 20 [EA] ^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 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

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

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

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

Treatment criteria:

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

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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	..	502.34	^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.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

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

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.

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.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

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

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

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

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

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **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.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **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.

Treatment criteria:

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

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

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**

- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.

Treatment criteria:

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

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

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

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

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

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. EST Monday to Friday).

tadalafil 20 mg tablet, 56

12150L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	502.34	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a Tadalca [CR]

■ DERMATOLOGICALS

■ ANTIPSORIATICS

ANTIPSORIATICS FOR SYSTEMIC USE

Psoralens for systemic use

■ METHOXSALLEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority required (STREAMLINED)

10989

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

Treatment criteria:

- Must be treated by a haematologist; OR

- Must be treated by a medical physician working under the supervision of a haematologist.
- A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12173Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.08	5	..	*226.28	Uvadex [TQ]

■ METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority required (STREAMLINED)**10971**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Population criteria:

- Patient must be aged 18 years or over.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12162D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	6	..	*443.58	Uvadex [TQ]

■ OTHER DERMATOLOGICAL PREPARATIONS**OTHER DERMATOLOGICAL PREPARATIONS***Agents for dermatitis, excluding corticosteroids***■ 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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
 All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note 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.servicesaustralia.gov.au or 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. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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 respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma adolescent and adult continuing PBS authority application form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) a completed Asthma Control Questionnaire (ACQ-5) score.

Authority required

Uncontrolled severe asthma

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or 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 condition prior to 1 April 2021, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- 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 a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have had a documented blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented total serum human immunoglobulin E greater than or equal to 30 IU/mL measured no more than 12 months prior to initiating a biological medicine, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating a biological medicine for this condition, **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 commencement of a biological medicine treatment for severe asthma, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine, **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 a biological medicine for this condition, **AND**
- Patient must not receive more than 24 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 with optimised asthma therapy and must be declared to have been met at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; **AND**

(b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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.

An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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.

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

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

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma dupilumab initial grandfather PBS authority application form which seeks details of the following (if not already provided):
 - (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) a eosinophil pathology report (eosinophil counts and dates) prior to initiating a biological medicine for this condition; or
 - (iii) IgE results prior to initiating a biological medicine for this condition; and
 - (iv) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose; and
 - (v) Date of commencing non-PBS-subsidised treatment with this drug.

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

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	..	1657.64	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological

medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

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

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

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **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 greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old, **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, **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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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.

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

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; or
 - (iv) the IgE result; and
 - (v) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

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

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) 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
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
 - (iii) eosinophil count and date; and
 - (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or
 - (v) the IgE results; and
 - (vi) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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	..	1657.64	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate

biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

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

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

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE 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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; or
 - (iv) the IgE result; and
 - (v) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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 greater than or equal to 30 IU/mL with a past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE 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.

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

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) 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
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
 - (iii) eosinophil count and date; and
 - (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or
 - (v) the IgE results; and
 - (vi) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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	..	1657.64	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note 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.servicesaustralia.gov.au or 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. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma adolescent and adult continuing PBS authority application form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) a completed Asthma Control Questionnaire (ACQ-5) score.

Authority required

Uncontrolled severe asthma

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or 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 condition prior to 1 April 2021, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- 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 a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have had a documented blood eosinophil count greater than or equal to 300 cells per microlitre measured no more than 12 months prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids, measured no more than 12 months prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented total serum human immunoglobulin E greater than or equal to 30 IU/mL measured no more than 12 months prior to initiating a biological medicine, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating a biological medicine for this condition, **AND**

- Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine, **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 a biological medicine for this condition, **AND**
- Patient must not receive more than 24 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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 with optimised asthma therapy and must be declared to have been met at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; **AND**
- (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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.

An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

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

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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.

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

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

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma dupilumab initial grandfather PBS authority application form which seeks details of the following (if not already provided):
 - (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) a eosinophil pathology report (eosinophil counts and dates) prior to initiating a biological medicine for this condition; or
 - (iii) IgE results prior to initiating a biological medicine for this condition; and
 - (iv) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose; and
 - (v) Date of commencing non-PBS-subsidised treatment with this drug.

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

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	..	1657.64	Dupixent [SW]

■ **SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

■ **PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Other anterior pituitary lobe hormones and analogues

■ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

11166Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*587.22	Somavert [PF]

■ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**

- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11174D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4226.35	Somavert [PF]

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11167R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4226.35	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11172B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4226.35	Somavert [PF]

HYPOTHALAMIC HORMONES

Somatostatin and analogues

■ LANREOTIDE

Authority required (STREAMLINED)

9261

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

9260

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

6423C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2232.74	Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

6425E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3686.66	Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

6424D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2955.64	Somatuline Autogel [IS]

■ LANREOTIDE

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

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

Authority required (STREAMLINED)

10077

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11527Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3686.66	Somatuline Autogel [IS]

■ OCTREOTIDE

Authority required (STREAMLINED)**9262**

Acromegaly

Clinical criteria:

- The condition must be controlled with octreotide immediate release injections, **AND**
 - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
 - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
 - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)**9313**

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)**9288**

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10549F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3527.40	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 10 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10566D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2661.50	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10558Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*4046.40	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

■ OCTREOTIDE

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

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

Authority required (STREAMLINED)**10077**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

11894B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*4046.40	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

■ OCTREOTIDE

Authority required (STREAMLINED)

9233

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
 - Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
 - The treatment must be after failure of other therapy including dopamine agonists; OR
 - The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
 - The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
 - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
 - The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
 - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)**9289**

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)**9232**

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

6227R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*651.64	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.05 [NV]

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

6229W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6242.26	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.5 [NV]

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

6228T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1284.16	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.1 [NV]

■ PASIREOTIDE EMBONATE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**

- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

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

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

d) a recent result of GH or IGF-1 levels must be provided.

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

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

Applications for 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

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10887B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.78	Signifor LAR [RJ]

pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10880P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.78	Signifor LAR [RJ]

pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10884W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.78	Signifor LAR [RJ]

■ **CALCIUM HOMEOSTASIS****ANTI-PARATHYROID AGENTS***Other anti-parathyroid agents*■ **CINACALCET**

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required (STREAMLINED)**10063**

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

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

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

cinacalcet 60 mg tablet, 28

11889R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*142.24	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

11888Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*209.46	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 30 mg tablet, 28

11891W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*76.42	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

■ **CINACALCET**

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

- Patient must have failed to respond to conventional therapy, **AND**

- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR

- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

cinacalcet 60 mg tablet, 28

9626P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*142.24	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

9627Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*209.46	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 30 mg tablet, 28

9625N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*76.42	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

ANTIINFECTIVES FOR SYSTEMIC USE
ANTIBACTERIALS FOR SYSTEMIC USE
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS
Macrolides
AZITHROMYCIN
Authority required (STREAMLINED)
9604

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

6221K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*122.98	Zithromax [PF]

NP

ANTIMYCOBACTERIALS
DRUGS FOR TREATMENT OF TUBERCULOSIS
Antibiotics
RIFABUTIN
Authority required (STREAMLINED)
9560

Mycobacterium avium complex infection

Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

Authority required (STREAMLINED)
9622

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

rifabutin 150 mg capsule, 30

6195C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*554.66	Mycobutin [PF]

NP

ANTIVIRALS FOR SYSTEMIC USE
DIRECT ACTING ANTIVIRALS
Nucleosides and nucleotides excl. reverse transcriptase inhibitors
GANCICLOVIR
Authority required (STREAMLINED)
9404

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)
9526

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

6136Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*249.24	^a Cymevene [PB]	^a GANCICLOVIR SXP [XC]

■ VALACICLOVIR

Authority required (STREAMLINED)

9267

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

6280M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*237.63	^a APO-Valaciclovir [TX] ^a Valaciclovir APOTEX [GX]	^a APX-Valaciclovir [TY] ^a Valaciclovir RBX [RA]
			^B 15.50	*253.13	^a Valtrex [RW]	

■ VALGANCICLOVIR

Authority required (STREAMLINED)

9316

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

6357N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1143.32	^a VALGANCICLOVIR HETERO [GG] ^a Valganciclovir Sandoz [SZ]	^a Valganciclovir Mylan [AF]

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9675F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*#4397.13	Valcyte [RO]

Antivirals for treatment of HCV infections

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
 - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
 - The treatment must be limited to a maximum duration of 16 weeks.
- The application must include details of the prior treatment regimen containing an NS5A inhibitor.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11337Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	18714.45	Maviret [VE]

NP

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11346E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	18714.45	Maviret [VE]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11355P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	1	..	18714.45	Maviret [VE]

■ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10653Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	1	..	11922.78	Harvoni [GI]

■ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10672Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11922.78	Harvoni [GI]

■ LEDIPASVIR + SOFOSBUVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10679C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	5	..	11922.78	Harvoni [GI]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

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

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 100

12809E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	2	..	*995.78	Ibavir [IX]

■ SOFOSBUVIR + VELPATASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11144M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	12547.78	Epclusa [GI]

■ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11659P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	12547.78	Vosevi [GI]

■ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
■ ANTINEOPLASTIC AGENTS
ANTIMETABOLITES
Pyrimidine analogues

■ AZACITIDINE

Note 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.

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

12784W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*1393.78	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

■ AZACITIDINE

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).
Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
 - 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
 - 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
 - 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
 - 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
 - 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
 - Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

- a completed authority prescription form; and
- a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- a copy of the full blood examination report; and
- a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

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

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6100C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*1393.78	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

■ AZACITIDINE

Note 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. EST Monday to Friday).

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6138C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*1393.78	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

■ DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority required (STREAMLINED)

9287

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

Authority required (STREAMLINED)

9223

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial

6249X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*937.30	^a Caelyx [BX]	^a Liposomal Doxorubicin SUN [RA]

PROTEIN KINASE INHIBITORS

Other protein kinase inhibitors

■ MIDOSTAURIN

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition; OR
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 56

11506N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	10254.28	Rydapt [NV]

■ MIDOSTAURIN

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

11518F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	20460.78	Rydapt [NV]

▪ MIDOSTAURIN

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

midostaurin 25 mg capsule, 112

11531X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	20460.78	Rydapt [NV]

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

■ RITUXIMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

rituximab 500 mg/50 mL injection, 50 mL vial

12721M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	569.83	^a Riximyo [SZ]	^a Truxima [EW]

■ RITUXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of

rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

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

Authority required (STREAMLINED)

9611

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

rituximab 500 mg/50 mL injection, 50 mL vial

11790M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*1128.64	^a Riximyo [SZ]	^a Truxima [EW]

▪ **RITUXIMAB**

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)

- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Authority required (STREAMLINED)

9640

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

Authority required (STREAMLINED)

9641

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

11810N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*682.24	^a Riximyo [SZ]	^a Truxima [EW]

rituximab 500 mg/50 mL injection, 50 mL vial

11804G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	..	..	*2209.50	^a Riximyo [SZ]	^a Truxima [EW]

▪ RITUXIMAB

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.
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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active microscopic polyangiitis
Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.
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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**

- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
- Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10583B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	232.60	^a Riximyo [SZ]	^a Truxima [EW]

rituximab 500 mg/50 mL injection, 50 mL vial

10576P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	569.83	^a Riximyo [SZ]	^a Truxima [EW]

▪ **RITUXIMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of

the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of

the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

rituximab 500 mg/50 mL injection, 50 mL vial

9611W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	569.83	^a Riximyo [SZ]	^a Truxima [EW]

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Authority required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**

- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)
8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)
8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)
8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)
8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)
8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)
8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5830W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*265.36	Nivestim [PF]

■ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)
8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)
8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)
8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)
8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)
8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)
8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)
8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*583.06	^a Zarzio [SZ]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

6127L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*583.08	^a Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	11	..	*583.06	^a Neupogen [AN]	^a Nivestim [PF]

■ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes and filgrastim 300 microgram/mL injection, 10 x 1 mL vials are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

6126K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*651.74	^a Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*366.66	^a Zarzio [SZ]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	11	..	*366.66	^a Neupogen [AN]	^a Nivestim [PF]

▪ **LIPEGFILGRASTIM**

Authority required (STREAMLINED)

9224

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

9322

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10931H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1222.78	Lonquex [TB]

▪ **PEGFILGRASTIM**

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Pelgraz or Ziextenzo is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Authority required (STREAMLINED)

9235

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

9303

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	368.03	^a Neulasta [JU] ^a Ristempa [JO] ^a Ziextenzo [SZ]	^a Pelgraz [OC] ^a Tezmota [JX]

Interferons

▪ **INTERFERON GAMMA-1B**

Authority required (STREAMLINED)

9639

Chronic granulomatous disease

Clinical criteria:

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

6148N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2258.58	Imukin [LM]

PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required (STREAMLINED)
9603

Chronic hepatitis C infection

Treatment criteria:

- Must be treated in an accredited treatment centre.

Population criteria:

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Clinical criteria:

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6449K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1266.36	Pegasys [RO]

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6439X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1100.02	Pegasys [RO]

Other immunostimulants
PLERIXAFOR

Note Special Pricing Arrangements apply.

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

Authority required (STREAMLINED)
9329

Mobilisation of haematopoietic stem cells

Clinical criteria:

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

10084R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	6689.23	Mozobil [GZ]

■ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

■ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 5 repeats will be authorised.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

- Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.
This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

12738K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	284.77	Orencia [BQ]

▪ **ABATACEPT**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide form weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of

rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Complex Drugs
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

9621J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	284.77	Orencia [BQ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required (STREAMLINED)

9589

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10246G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*32520.67	Lemtrada [GZ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required (STREAMLINED)

9636

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10243D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*54169.28	Lemtrada [GZ]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 $\mu\text{mol/L}$, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

- presence of schistocytes on blood film;
- low or absent haptoglobin;
- lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
- a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
- a sCr of greater than the age-appropriate ULN in paediatric patients; or
- a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and
- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10182X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5688.41	Soliris [XI]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10192K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5688.41	Soliris [XI]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

- An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- an eGFR within +/- 25% from baseline; or
- an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- A completed authority prescription form; and
- A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
- A detailed cover letter from the prescriber; and
- A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- A measurement of body weight at the time of application; and
- An identified genetic mutation, if applicable; and
- A family history of aHUS, if applicable; and

- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10521R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	5688.41	Soliris [XI]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
 - (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
 - (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
 - (3) A detailed cover letter from the prescriber; and
 - (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
 - (5) A measurement of body weight at the time of application; and
 - (6) An identified genetic mutation, if applicable; and
 - (7) A family history of aHUS, if applicable; and
 - (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
 - (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
 - (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
 - (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
 - (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
 - (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
 - (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10⁹/L);OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
 - (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
 - (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application, and
- (7) An identified genetic mutation, if applicable; and
- (8) A family history of aHUS if applicable; and
- (9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
- (10) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (11) An inclusion of the individual consequences of recurrent disease; and
- (12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and

- (6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant if applicable (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10194M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5688.41	Soliris [XI]

■ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9691

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9693

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

everolimus 750 microgram tablet, 60

6461C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*2348.90	^a Certican [NV]	^a Everocan [CR]

everolimus 250 microgram tablet, 60

6459Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*406.64	^a Certican [NV]	^a Everocan [CR]

everolimus 500 microgram tablet, 60

6460B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*805.50	^a Certican [NV]	^a Everocan [CR]

everolimus 1 mg tablet, 60

9582H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*3115.94	^a Certican [NV]	^a Everocan [CR]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9691

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9693

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

6364Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*\$519.57	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

6209T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*\$282.10	^a APO-Mycophenolate [TX] ^a Ceptolate [AF] ^a Mycophenolate APOTEX [GX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a MycoCept [RF] ^a Mycophenolate GH [GQ] ^a Pharmacor Mycophenolate 500 [CR]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority required (STREAMLINED)

9692

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9809

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

Clinical criteria:

- The condition must be proven by biopsy.

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

mycophenolate 180 mg enteric tablet, 120

6369F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*\$186.22	Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

6370G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*\$364.62	Myfortic [NV]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Note Pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9689

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9690

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 250 mg capsule, 100

6208R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*\$282.22	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

mycophenolate mofetil 250 mg capsule, 50

1837Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*\$282.22	^a Ceptolate [AF]

■ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required (STREAMLINED)

9744

Clinically definite relapsing-remitting multiple sclerosis

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9624M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1316.12	Tysabri [BD]

■ OCRELIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9523

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

9635

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11237K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*17580.78	Ocrevus [RO]

■ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
9914

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

sirolimus 2 mg tablet, 100

6457W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2397.90	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*968.76	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*618.82	Rapamune [PF]

sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1222.82	Rapamune [PF]

VEDOLIZUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be

authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- faeces: higher than normal lactoferrin or calprotectin level; or
- diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **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.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
 - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
 - (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10415E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2997.71	Entyvio [TK]

▪ **VEDOLIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

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

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

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

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

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

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Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

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

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

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10398G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2997.71	Entyvio [TK]

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

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)

12116

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

12384T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	859.06	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12349Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*859.06	Amgevita [AN]

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

12368Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	859.06	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ ADALIMUMAB

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. EST Monday to Friday).

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12715F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	859.06	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

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

12732D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

ADALIMUMAB

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. EST Monday to Friday).

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

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

12731C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	859.06	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

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

12749B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021,

AND

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12674C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*859.06	^a Amgevita [AN]

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12686Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for 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 active juvenile idiopathic arthritis

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

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form; and

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form; and

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

(1) a completed authority prescription form; and

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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 active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

(1) a completed authority prescription form; and

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

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

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

Applications for 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

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

9680L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	859.06	^a Amgevita [AN]	^a Hadlima [RF]
					^a Hyrimoz [SZ]	^a Idacio [PK]

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

12335F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

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

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form; and

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9679K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	859.06	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

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

12396K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Applications for 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:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

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

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form; and

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

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12439Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*859.06	^a Amgevita [AN]

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12443X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	859.06	^a Humira [VE]

■ ETANERCEPT

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

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

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

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12757K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	984.60	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12736H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	984.60	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

12734F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	496.20	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for 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 active juvenile idiopathic arthritis

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

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9615C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	984.60	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9641K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	984.60	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

6367D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	496.20	Enbrel [PF]

■ INFILIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one

time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6.

A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

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

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

Applications for 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 Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

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

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

infliximab 100 mg injection, 1 vial

11399Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they

continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

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

Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11412P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB
Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

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

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a

treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements. (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

infliximab 100 mg injection, 1 vial

11445J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within

these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

11487N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

9632

Acute severe ulcerative colitis

Treatment criteria:

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

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAL score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10057H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*1651.33	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [OQ]	

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

12051

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11396T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

▪ **INFLIXIMAB**

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

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

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
 - a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn

disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatal of conventional therapies is not required.

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

Authority required (STREAMLINED)

9775

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

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

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11450P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9621

Ankylosing spondylitis

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 ankylosing spondylitis.

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 aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11488P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	3	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines.

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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11498E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-

subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

Initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and

immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or

continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11797X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having

to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they

continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

12067

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The 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.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11483J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*1008.40	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

9732

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

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

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11432Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines. 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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

9472

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11515C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis

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 ankylosing spondylitis.

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 aged 18 years or older.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

11489Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

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

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11590B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 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 Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

9602

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

9584

Severe chronic plaque psoriasis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11595G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy -

Initial 1 treatment (new patient); or,
 (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
 (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
 (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required (STREAMLINED)

12074

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11796W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1651.33	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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

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

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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

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

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

infliximab 100 mg injection, 1 vial

12751D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of

repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy

of less than 5 years) [further details are under 'Swapping treatment' below]; or
 (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or
 (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response. For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:
 - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic scoreless than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and

- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
- (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.
- Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR

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

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

10184B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

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

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that

they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
- (ii) details of prior biological medicine treatment including details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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
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Authority required

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

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

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

Applications for 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

infliximab 100 mg injection, 1 vial

9612X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [OQ]	

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6.

A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

- (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
- (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

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Or mailed to:

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Complex Drugs
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or
 - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
 - (iii) the date of clinical assessment; and
 - (iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

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

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR

- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

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

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

Applications for 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 Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

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

infliximab 100 mg injection, 1 vial

9613Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended

that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflextra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

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

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

Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
- details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

9674E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialed and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6397Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB
Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

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

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (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
- 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- 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 initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

- (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a completed BASDAI Assessment Form; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a

minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for 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

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

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

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6448J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines.

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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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
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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date

of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6496X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

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

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and

scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial 1 - Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of

at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

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

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.
- An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

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

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

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

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for 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 chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

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

infliximab 100 mg injection, 1 vial

9617E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	341.32	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

Interleukin inhibitors

▪ **ANAKINRA**

Note This drug is not PBS-subsidised for conditions other than CAPS.

Authority required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

10263E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1458.53	Kineret [ZO]

▪ **TOCILIZUMAB**

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

- (1) a completed authority prescription form; and

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

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 200 mg/10 mL injection, 10 mL vial

12766X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

12787B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12805Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	Actemra [RO]

■ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

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

(1) a completed authority prescription form; and

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

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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

(1) a completed authority prescription form; and

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

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

tocilizumab 200 mg/10 mL injection, 10 mL vial

12795K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

12811G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12810F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to

have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle.

Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 400 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 400 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

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

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

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retreatment or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retreat or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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

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

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials

12705Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*2308.06	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12728X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2306.86	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	^a Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and

submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

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

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

Applications for 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 active juvenile idiopathic arthritis

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

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
 - Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
 - The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

10079L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10068X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10060L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	Actemra [RO]

▪ **TOCILIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

- 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 biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
 - a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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

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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR

- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

10071C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10073E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10078K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	Actemra [RO]

■ TOCILIZUMAB
Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or
- (iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).
- (iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a

treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 80 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 80 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
- (ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

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

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

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

12693C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	529.11	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	^a Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials

12727W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*530.31	^a RoActemra [DZ]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity

(joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle.

Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 200 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 200 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

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

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Systemic juvenile idiopathic arthritis

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

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

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

12726T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1209.39	^a RoActemra [DZ]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1423X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	^a Actemra [RO]

tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials

12747X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*1210.59	^a RoActemra [DZ]

■ **TOCILIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24

months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide form weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the

required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted

following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

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

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

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

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for 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 active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	219.66	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	93.97	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	429.39	Actemra [RO]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to

have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6.

A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional

therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

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

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

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

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

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- patient must have evidence of intestinal inflammation;
- patient must be assessed clinically as being in a high faecal output state;
- patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- faeces: higher than normal lactoferrin or calprotectin level; or
- diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- two completed authority prescription forms; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:
 - the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
 - the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

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

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11164N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*15284.10	Stelara [JC]

Calcineurin inhibitors

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9831

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6109M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	65.88	Sandimmun [NV]

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9764

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9695

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)
9763

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a dermatologist.

Authority required (STREAMLINED)
9694

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)
9742

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

6232B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*86.18	Neoral 10 [NV]

ciclosporin 50 mg capsule, 30

6353J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*286.66	^a APO-Ciclosporin [TX] ^a Neoral 50 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 25 mg capsule, 30

6352H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*141.82	^a APO-Ciclosporin [TX] ^a Neoral 25 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 100 mg/mL oral liquid, 50 mL

6125J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1310.94	Neoral [NV]

ciclosporin 100 mg capsule, 30

6354K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*576.02	^a APO-Ciclosporin [TX] ^a Neoral 100 [NV]	^a Cyclosporin Sandoz [SZ]

■ TACROLIMUS
Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
9697

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

tacrolimus 2 mg capsule, 100

10879N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1047.78	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11920J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	3	..	*692.30	ADVAGRAF XL [LQ]

tacrolimus 750 microgram capsule, 100

10875J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*397.78	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

6216E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*464.14	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 1 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule, 100

6328C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*235.96	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 0.5 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 5 mg capsule, 50

6217F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1144.22	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 5 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9683P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*788.24	ADVAGRAF XL [LQ]

tacrolimus 500 microgram modified release capsule, 30

9681M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*86.82	ADVAGRAF XL [LQ]

tacrolimus 1 mg modified release capsule, 60

9682N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*281.60	ADVAGRAF XL [LQ]

Other immunosuppressants

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
 - Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
 - The treatment must be in combination with bortezomib and dexamethasone, **AND**
 - The treatment must not exceed a total of 2 cycles under this restriction.
- Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12050F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4752.20	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12038N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4543.00	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12011E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5534.38	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12037M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5976.52	Revlimid [CJ]

▪ **LENALIDOMIDE**

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's medical records.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12060R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4752.20	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12071H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4543.00	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12020P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5534.38	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12068E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5976.52	Revlimid [CJ]

■ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

- (a) a completed authority prescription form; and
- (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
- (g) a signed patient acknowledgement 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. EST Monday to Friday).

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

Applications for 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

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**

- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**

- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
- (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note 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. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

2796E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4752.20	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

2798G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4543.00	Revlimid [CJ]

■ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

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

Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4752.20	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4543.00	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5534.38	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5976.52	Revlimid [CJ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and

(3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (lenalidomide and dexamethasone), or, in patients initiated on triple therapy (lenalidomide, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4752.20	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4543.00	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5534.38	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5976.52	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the date the autologous stem cell transplant was performed, and nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the results of current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

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

Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

lenalidomide 5 mg capsule, 28

11966T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6041.40	Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11969Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6320.34	Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11965R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7363.24	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's medical records.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

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

Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
 - Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
 - The treatment must be in combination with bortezomib and dexamethasone, **AND**
 - The treatment must not exceed a total of 4 cycles under this restriction.
- Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

lenalidomide 15 mg capsule, 14

12069F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3705.51	Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12018M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4000.27	Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12058P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3044.59	Revlimid [CJ]

lenalidomide 10 mg capsule, 14

12004T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3184.06	Revlimid [CJ]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

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

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
 - The treatment must be in combination with bortezomib and dexamethasone, **AND**
 - Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
 - Patient must have undergone or be ineligible for a stem cell transplant, **AND**
 - Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

pomalidomide 3 mg capsule, 14

12668R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6697.78	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12661J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6697.78	Pomalyst [CJ]

■ **POMALIDOMIDE**

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

If treatment with either bortezomib or lenalidomide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to either bortezomib or lenalidomide treatment develops during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide; and
- (4) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following:
 - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10022.78	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10022.78	Pomalyst [CJ]

■ THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required (STREAMLINED)

9290

Multiple myeloma

thalidomide 50 mg capsule, 28

6469L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*1412.38	Thalomid [CJ]

thalidomide 100 mg capsule, 28

9684Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1412.36	Thalomid [CJ]

■ MUSCULO-SKELETAL SYSTEM

■ MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

■ BACLOFEN

Authority required (STREAMLINED)

9562

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

9525

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

9638

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)

9606

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11194E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*804.66	Sintetica Baclofen Intrathecal [BZ]

■ BACLOFEN

Note Pharmaceutical benefits that have the forms baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules and baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

9488

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

9637

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

9489

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)**9524**

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11128Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1004.10	^a Sintetica Baclofen Intrathecal [BZ]

baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

11420C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1004.10	^a Bacthecal [DZ]

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

6284R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1004.08	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

■ IBANDRONATE

Authority required (STREAMLINED)**9333**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

ibandronate 6 mg/6 mL injection, 6 mL vial

9619G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	311.31	Bondronat [IX]

■ PAMIDRONATE DISODIUM

Authority required (STREAMLINED)**9234**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

6288Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	67.04	Pamisol [PF]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

6287X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*67.04	Pamisol [PF]

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

6286W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*67.02	Pamisol [PF]

■ PAMIDRONATE DISODIUM

Authority required (STREAMLINED)**9234**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required (STREAMLINED)**9335**

Multiple myeloma

Authority required (STREAMLINED)

9315

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

6289B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	94.67	Pamisol [PF]

▪ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**9268**

Multiple myeloma

Authority required (STREAMLINED)**9328**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority required (STREAMLINED)**9304**

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

Authority required (STREAMLINED)**9317**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

6371H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	84.58	^a APO-Zoledronic Acid [TX] ^a Zometa [SA]	^a DEZTRON [DZ]

▪ OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM**OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM***Other drugs for disorders of the musculo-skeletal system***▪ NUSINERSEN**

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL injection, 5 mL vial

11476B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110047.78	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- Onset between 6 and 18 months; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Weakness in trunk righting/derotation; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- Onset between 18 months and 3 years of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or

- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s).

nusinersen 12 mg/5 mL injection, 5 mL vial

11472T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110047.78	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - (i) confirmation of genetic diagnosis of SMA; and
 - (ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

nusinersen 12 mg/5 mL injection, 5 mL vial

12176W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110047.78	Spinraza [BD]

■ RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with standard of care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12609P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	12192.50	Evrysdi [RO]

■ RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must be 18 years of age or under.
- Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s).

Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Transitioning from non-PBS to PBS subsidised treatment - Grandfather treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2021, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must be responding to non-PBS subsidised risdiplam for this condition at the time of application.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must have been 18 years of age or under at the time non-PBS subsidised treatment with this drug was initiated for this condition.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s).

Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12610Q	±1	..	12192.50	Evrysdi [RO]

■ **NERVOUS SYSTEM**

■ **ANTI-PARKINSON DRUGS**

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

■ **LEVODOPA + CARBIDOPA**

Note Special Pricing Arrangements apply.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10161

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11910W	4	5	..	*5815.78 Duodopa [VE]

■ **LEVODOPA + CARBIDOPA**

Note Special Pricing Arrangements apply.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10363

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR

- Patient must require a total daily dose of more than 2000 mg of levodopa.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9744W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11583.78	Duodopa [VE]

Dopamine agonists**■ APOMORPHINE****Authority required (STREAMLINED)****10830**

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

11083H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	5	..	*7475.08	Apomine Solution for Infusion [PF]

■ APOMORPHINE**Authority required (STREAMLINED)****11445**

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

9640J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8064.94	Movapo [TD]

apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules

9607P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	72	5	..	*6417.22	Movapo [TD]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

10971K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8064.94	Movapo PFS [TD]

■ APOMORPHINE**Note** No increase in the maximum quantity or number of units may be authorised.**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.**Authority required (STREAMLINED)****10830**

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

11475Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2635.78	^a Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

11688E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2635.78	^a Apomine Intermittent [PF]

■ PSYCHOLEPTICS**ANTIPSYCHOTICS***Diazepines, oxazepines, thiazepines and oxepines***■ CLOZAPINE****Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.**Authority required (STREAMLINED)****9490**

RESPIRATORY SYSTEM

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

11415T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	148.18	Versacloz [PF]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Pfizer ClopineCentral.

Authority required (STREAMLINED)

9490

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*76.42	Clopine 25 [PF]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*142.24	Clopine 50 [PF]

clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	148.18	Clopine Suspension [PF]

clozapine 100 mg tablet, 100

6102E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.86	Clopine 100 [PF]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

6418T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*511.94	Clopine 200 [PF]

■ RESPIRATORY SYSTEM

■ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

■ BENRALIZUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must 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	..	..	3358.78	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Continuing PBS Authority Application - Supporting Information Form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) 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	..	3358.78	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; and
 - (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:

- (i) 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
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
- (iii) eosinophil count and date; and
- (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

benralizumab 30 mg/mL injection, 1 mL pen device

11997K	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	3358.78	Fasenra Pen [AP]

■ 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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must 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	..	..	1685.78	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

11829N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1685.78	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological

medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, 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.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Continuing PBS Authority Application - Supporting Information Form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) 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	..	1685.78	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

11014Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1685.78	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; and
 - (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) 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
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
 - (iii) eosinophil count and date; and
 - (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
 - (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- A respiratory physician; and

RESPIRATORY SYSTEM

- A pharmacist, nurse or asthma educator.

mepolizumab 100 mg/mL injection, 1 mL pen device

12051G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1685.78	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

11003D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1685.78	Nucala [GK]

■ OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
 - (i) demonstration of failure to achieve an adequate response to standard therapy; and
 - (ii) drug names and doses of standard therapies that the patient has failed; and
 - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 150 mg/mL injection, 1 mL syringe

11175E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*860.58	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where

they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11826K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11825J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	434.18	Xolair [NV]

■ OMALIZUMAB**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing restriction may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Balance of supply in a patient aged 6 to 12 years

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11958J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11932B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	434.18	Xolair [NV]

■ OMALIZUMAB

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

11163M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*860.58	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
 All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

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.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 must be made at around 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 and for the application for 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Asthma PBS Authority Application and Supporting Information Form which includes details of:
 - (i) maintenance oral corticosteroid dose; or
 - (ii) Asthma Control Questionnaire (ACQ-5) score including the date of assessment of the patient's symptoms; or
 - (iii) for patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the exacerbation rate has reduced.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11840E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11864K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	434.18	Xolair [NV]

■ OMALIZUMAB**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy.

- (a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

- (b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

- (2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

- (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab

therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 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.humanservices.gov.au or 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 allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of:
 - (i) maintenance oral corticosteroid dose; and
 - (ii) Asthma Control Questionnaire (ACQ-5) score; or
 - (iii) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11952C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11953D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	434.18	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a

treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old at the time of application, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 initial IgE assessment must be no more than 12 months old at the time of 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma PBS Authority Application - Supporting Information Form, which includes the following:

- (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
- (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (iii) the IgE result; and
- (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma (omalizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:

- (i) 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
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
- (iii) the IgE results; and
- (iv) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	434.18	Xolair [NV]

■ OMALIZUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

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 For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 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.humanservices.gov.au or 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 allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **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, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), **AND**

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the IgE result; and
 - (iv) Asthma Control Questionnaire (ACQ-5) score; or
 - (v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10956P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	220.98	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

10968G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	434.18	Xolair [NV]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

9624

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)

9591

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required (STREAMLINED)

9592

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

6120D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1964.70	Pulmozyme [RO]

■ **MANNITOL**

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

9527

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)

9593

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

mannitol 40 mg powder for inhalation, 280 capsules

2008Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1836.98	Bronchitol [HT]

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

■ IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 12 months or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
 - (3) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
 - (4) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.
- Note:** FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
 - (6) sweat chloride result; and
 - (7) height and weight measurements at the time of application; and
 - (8) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 12 months or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
- (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

ivacaftor 50 mg granules, 56 sachets

11097C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21422.78	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10175M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21422.78	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11109Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21422.78	Kalydeco [VR]

■ LUMACFTOR + IVACFTOR**Note Managed Access Program:**

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11463H	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	17860.28	Orkambi [VR]

■ LUMACAFTOR + IVACAFTOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and

- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11464J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	17860.28	Orkambi [VR]

■ LUMACAFITOR + IVACAFITOR**Note Managed Access Program:**

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11841F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	17860.28	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11848N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	17860.28	Orkambi [VR]

■ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data for tezacaftor with ivacaftor for children aged 12 years and over, as well as on the basis of 96 weeks of data for lumacaftor with ivacaftor in children aged 12 years and over who are homozygous for the F508del mutation. Information about the long term benefits of this medicine and lumacaftor with ivacaftor for patients who are homozygous for the F508del mutation will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient having at least one RF mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11833T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19997.78	Symdeko [VR]

■ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**Note Managed Access Program:**

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 48 weeks of data for this medicine and 96 weeks of data for lumacaftor with ivacaftor in children aged 12 years and over. Information about the long term benefits of this medicine and lumacaftor with ivacaftor will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and

- (6) height and weight measurements at the time of application; and
 (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11834W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19997.78	Symdeko [VR]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 180 mg tablet, 30

11546Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*1319.98	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 360 mg tablet, 30

11496C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*2592.10	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11545P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*669.34	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

▪ **DEFERASIROX**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 250 mg dispersible tablet, 28

6500D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*1235.14	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

6499C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*625.24	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

9600G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2422.48	Deferasirox Juno [JU]

▪ **DEFERASIROX****Authority required (STREAMLINED)****9302**

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority required (STREAMLINED)**9222**

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority required (STREAMLINED)**9258**

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.**deferasirox 180 mg tablet, 30**

11510T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*1319.98	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 250 mg dispersible tablet, 28

11238L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*1235.14	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

11236J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*625.24	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11243R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*2422.48	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

11547R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2592.10	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11548T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*669.34	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

■ DEFERASIROX**Note** A patient's median life expectancy is determined by the severity of their underlying disease.**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 180 mg tablet, 30

11557G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*1319.98	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB]

^a Eferas [AF] ^a Jadenu [NM]
^a Pharmacor Deferasirox FC [CR]

deferasirox 360 mg tablet, 30

11511W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2592.10	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11558H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*669.34	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

■ DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 250 mg dispersible tablet, 28

11244T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*1235.14	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

11241P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*625.24	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11232E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*2422.48	Deferasirox Juno [JU]

■ DEFERIPRONE**Authority required (STREAMLINED)**

9286

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority required (STREAMLINED)

9228

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 100 mg/mL oral liquid, 250 mL

9638G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*1009.38	Ferriprox [EU]

deferiprone 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
6416Q	3	5	..	*1203.46	Feriprox [EU]

■ DEFERIPRONE**Authority required (STREAMLINED)****9623**

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority required (STREAMLINED)**9590**

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 1 g tablet, 50

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11724C	6	5	..	*2359.18	Feriprox [EU]

■ DESFERRIOXAMINE**Authority required (STREAMLINED)****9696**

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

desferrioxamine mesilate 2 g injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
6270B	60	5	..	*1916.38	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 500 mg injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
6113R	40	5	..	*5602.98	DBL Desferrioxamine Mesilate [PF]

Drugs for treatment of hyperkalemia and hyperphosphatemia**■ LANTHANUM****Authority required (STREAMLINED)****9762**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 750 mg chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9636E	2	5	..	*710.76	Fosrenol [TK]

lanthanum 500 mg chewable tablet, 2 x 45

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9635D	2	5	..	*473.30	Fosrenol [TK]

lanthanum 1 g chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9637F	2	5	..	*799.18	Fosrenol [TK]

■ SEVELAMER

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority required (STREAMLINED)**9762**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9620H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*376.44	^a Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

11838C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*376.44	^a Sevelamer Apotex [TX]	^a Sevelamer Lupin [GQ]

■ SUCROFERRIC OXYHYDROXIDE**Authority required (STREAMLINED)****9762**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10230K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*752.20	Velphoro [VL]

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ALIMENTARY TRACT AND METABOLISM

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Various alimentary tract and metabolism products

■ TEDUGLUTIDE

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment, **AND**
- The treatment must provide no more than the balance of up to 12 months of treatment.

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11808L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	21840.00	Revestive [TK]

■ TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
 - Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
 - Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks, **AND**
 - Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
 - The treatment must not exceed 12 months under this restriction, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition.
- Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:
- for a patient of any age, the mean number of days of parenteral support per week
 - for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over the four weeks immediately prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i). Assessment of treatment response/non-response in the 'First continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

teduglutide 5 mg injection [28 vials] (& inert substance diluent [28 x 0.5 mL syringes], 1 pack

11793Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	21840.00	Revestive [TK]

▪ TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Type III Short bowel syndrome with intestinal failure

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment with this drug for this condition as a grandfathered patient, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; OR
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline.

Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period.

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period.

From 1 September 2021

Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:

- a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and
- the current value (observed over the preceding 4 weeks)

Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); 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).

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have received PBS-subsidised first-continuing treatment with this drug for this condition and achieved a treatment response in the preceding treatment period; OR
- Patient must have received PBS-subsidised recommencement of treatment following a trial cessation period and not have previously experienced a failure to respond to treatment with this drug for this condition.

Treatment response**Adult:**

In a subsequent continuing treatment application, treatment response in a patient aged at least 18 years is one of:

- (i) a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment for PBS-subsidised treatment; or
- (ii) parenteral support completely ceasing (due to clinical benefit from this drug) for a period of at least 4 consecutive weeks

Child (yet to turn 18 years of age):

In a subsequent continuing treatment application, treatment response in a child is one of:

- (iii) a reduction in the mean number of days of parenteral support of at least 1 day per week since the last assessment for PBS-subsidised treatment; or
- (iv) a reduction in the mean weekly volume of parenteral support (mL per kg of body weight) of at least 20% since the last assessment for PBS-subsidised treatment; or
- (v) parenteral support completely ceasing (due to clinical benefit from this drug) for a period of at least 4 consecutive weeks.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over the immediately preceding 4 week treatment period.

Treatment failure**Adult:**

In a subsequent continuing treatment application, treatment failure is defined as an increase in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to the most recent authority application.

Child (yet to turn 18 years of age):

In a subsequent continuing treatment application, treatment failure is defined as at least one of the following occurring:

- (i) an increase in the mean number of days per week in parenteral support (parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to the most recent authority application; or
- (ii) an increase of 20% or more in the mean weekly volume of parenteral support (mL per kg of body weight; parenteral nutrition with or without IV fluids) to meet caloric, fluid or electrolyte needs, compared to most recent authority application.

Patients who experience failure of treatment must permanently discontinue treatment.

Treatment stability

A patient who neither demonstrates a treatment response as defined above nor a treatment failure as defined above since the last assessment for PBS-subsidised treatment is considered to have 'treatment stability'.

Trial cessation period

A patient with treatment stability must undertake a trial cessation period. A patient who re-commences treatment after a trial cessation period is exempt from further trial cessation periods.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Recommencement of treatment

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have undertaken a trial cessation period due to experiencing a stable parenteral support regimen in the first continuing or subsequent continuing treatment phase, and not due to a treatment failure; OR
- Patient must have undertaken a trial cessation period for any medical reason other than lack of treatment efficacy, **AND**
- Patient must have experienced deterioration during a trial cessation period.

Deterioration during the trial cessation period includes an increase in parenteral support use, as well as changes in renal function, urinary sodium levels and changes in body weight in the absence of an increase in parenteral support use. This is not an exhaustive list of the signs/symptoms of disease deterioration - the treating physician must be satisfied that in the absence of treatment with this drug, the patient's condition has deteriorated.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

BLOOD AND BLOOD FORMING ORGANS

(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).

Note Authority applications to continue treatment after this application should occur under the 'Subsequent continuing treatment' phase.

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11794R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21840.00	Revestive [TK]

■ BLOOD AND BLOOD FORMING ORGANS

■ ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

■ ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must not have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with romiplostim for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
- (3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 thrombocytopenia

Treatment Phase: Second or subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than 4 weeks old at the time of application.

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Note 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. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note 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. EST Monday to Friday).

eltrombopag 25 mg tablet, 28

5825N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1292.76	Revolade [NV]

eltrombopag 50 mg tablet, 28

5826P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2585.52	Revolade [NV]

▪ ROMIPLOSTIM**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have had a splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy following the splenectomy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy following the splenectomy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 thrombocytopenia

Treatment Phase: Initial treatment 2 - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must not have had a splenectomy, **AND**

- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- Patient must be unsuitable for splenectomy due to medical reasons, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

Where intolerance to treatment with corticosteroid and immunoglobulin therapy developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be requested by telephone. The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form,
- (3) details of a platelet count supporting the diagnosis of ITP, and
- (4) details of the reason of medical contraindication for surgery and date of assessment.

The platelet count must be no more than 4 weeks old at the time of application.

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, **AND**
- Patient must not have previously received PBS-subsidised continuing treatment with eltrombopag for this condition, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised treatment with this drug,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Applications for the First continuing PBS-subsidised treatment or Re-initiation of interrupted PBS-subsidised continuing treatment must be made in writing and must include:

- (1) a completed authority prescription form, and
- (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form, and
- (3) the most recent platelet count.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug.

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

Population criteria:

- Patient must be aged 18 years or older.

For the purpose of this restriction, a continuing response to treatment with drug is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with this drug

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L
OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

The platelet count must be no more than 4 weeks old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Note 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. EST Monday to Friday).

Authority required

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy within 24 weeks initial treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 restriction to complete 24 weeks treatment; OR
- Patient must be swapping therapy from eltrombopag to this drug for this condition within the initial 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second and subsequent Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be aged 18 years or older.

BLOOD AND BLOOD FORMING ORGANS

Patients will be able to trial either eltrombopag or romiplostim within the initial 24 weeks treatment period. Where a patient has started initial treatment with one of the two agents, change of therapy to the alternative agent may be authorised under the Balance of supply or change of therapy restriction to complete up to 24 weeks initial treatment. Patients who fail to demonstrate a response to treatment with eltrombopag and/or romiplostim after completion of 24 weeks initial therapy will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note 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. EST Monday to Friday).

romiplostim 250 microgram injection, 1 vial

9696H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	494.12	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9698K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	988.24	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required (STREAMLINED)

6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5640W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*856.94	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL pen device

5650J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*3004.64	Aranesp SureClick [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL pen device

5648G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1637.60	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5651K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2016.56	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5638R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*516.04	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL pen device

5647F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1244.08	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL pen device

5649H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2016.48	Aranesp SureClick [AN]

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5637Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*274.02	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5642Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1244.06	Aranesp [AN]

darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5639T	2	5	..	*706.00	Aranesp [AN]

darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5641X	2	5	..	*1059.46	Aranesp [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5644C	2	5	..	*1637.54	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5645D	8	5	..	*516.08	Aranesp SureClick [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL pen device

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5646E	8	5	..	*856.88	Aranesp SureClick [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5643B	2	5	..	*3004.62	Aranesp [AN]

▪ EPOETIN ALFA**Authority required (STREAMLINED)****6294**

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5721D	2	5	..	*653.56	Eprex 4000 [JC]

epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5714R	2	5	..	*214.92	Eprex 1000 [JC]

epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5719B	2	5	..	*397.70	Eprex 2000 [JC]

epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5715T	2	5	..	*813.66	Eprex 5000 [JC]

epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5722E	2	5	..	*1516.18	Eprex 10000 [JC]

epoetin alfa 40 000 units/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5718Y	2	5	..	*964.98	Eprex 40,000 [JC]

epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5720C	2	5	..	*513.20	Eprex 3000 [JC]

epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5717X	2	5	..	*1252.72	Eprex 8000 [JC]

BLOOD AND BLOOD FORMING ORGANS

epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5713Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2982.68	Eprex 20,000 [JC]

epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5716W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*965.86	Eprex 6000 [JC]

▪ EPOETIN BETA

Authority required (STREAMLINED)

6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes

5726J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*687.96	NeoRecormon [RO]

epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes

5728L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1016.70	NeoRecormon [RO]

epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes

5727K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*856.50	NeoRecormon [RO]

epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5725H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*540.22	NeoRecormon [RO]

epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

5729M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1595.98	NeoRecormon [RO]

epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes

5724G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*418.62	NeoRecormon [RO]

▪ EPOETIN LAMBDA

Authority required (STREAMLINED)

6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

9587N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*687.94	Novicrit [SZ]

epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

9668W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*226.24	Novicrit [SZ]

epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

9594Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1318.60	Novicrit [SZ]

epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

9589Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*856.46	Novicrit [SZ]

epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

9591T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1016.66	Novicrit [SZ]

epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes

9596C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1595.96	Novicrit [SZ]

epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

9670Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*540.20	Novicrit [SZ]

epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes

9669X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*418.60	Novicrit [SZ]

■ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**Authority required (STREAMLINED)****6294**

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe

5799F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1558.72	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe

5800G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2694.58	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe

5797D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*938.68	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe

5796C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*725.80	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe

5795B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*498.42	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe

5794Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*299.06	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe

5798E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1086.76	Mircera [RO]

■ CARDIOVASCULAR SYSTEM**■ ANTIHYPERTENSIVES****OTHER ANTIHYPERTENSIVES***Antihypertensives for pulmonary arterial hypertension***■ AMBRISENTAN**

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

ambrisentan 10 mg tablet, 30

5608E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

5607D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^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.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

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. EST Monday to Friday).

ambrisentan 10 mg tablet, 30

12186J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

ambrisentan 5 mg tablet, 30

12212R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1844.54	^a Ambrisentan Mylan [AF] ^a PULMORIS [YC]	^a Cipla Ambrisentan [LR] ^a Volibris [ZE]

■ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

- Patient must be receiving PBS-subsidised treatment with this PAH agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

bosentan 62.5 mg tablet, 60

12140Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

■ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note 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 dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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.

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	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

■ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
 - The treatment must be the sole PBS-subsidised PAH agent for this condition.
- The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

bosentan 125 mg tablet, 60

5619R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a Tracleer [JC]

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	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

■ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

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.

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. EST Monday to Friday).

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	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan RBX [RA] ^a Tracleer [JC]	^a Bosentan Cipla [LR] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]

▪ **BOSENTAN**

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

bosentan 125 mg tablet, 60

12149K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	430.63	^a Bosentan APO [GX] ^a BOSENTAN DR.REDDY'S [RI] ^a Bosentan Mylan [AF] ^a BOSLEER [RW]	^a Bosentan Cipla [LR] ^a Bosentan GH [GQ] ^a Bosentan RBX [RA] ^a Tracleer [JC]

▪ **EPOPROSTENOL**

Note Pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial & diluent and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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'.

epoprostenol 1.5 mg injection, 1 vial

10117L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	30	5	..	*1779.90	^a EPOPROSTENOL SUN [RA]	^a Veletri [JC]

epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack

11065J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*1779.90	^a Flolan [GK]

■ EPOPROSTENOL

Note Pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial & diluent and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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'.

epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack

11090Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*890.10	^a Flolan [GK]

epoprostenol 500 microgram injection, 1 vial

10130E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	30	5	..	*998.40	^a EPOPROSTENOL SUN [RA]	^a 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have documented PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. 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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, a phosphodiesterase-5 inhibitor is one of: (a) sildenafil, (b) tadalafil; a prostanoid is one of: (c) epoprostenol, (d) iloprost.

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.

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. EST 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'.

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; OR
- The treatment must have been initiated as part of non-PBS-subsidised dual therapy for an untreated patient with 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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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'.

iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

5751Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	349.59	Ventavis [BN]

■ MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

macitentan 10 mg tablet, 30

10136L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2732.65	Opsumit [JC]

■ MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

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. EST Monday to Friday).

macitentan 10 mg tablet, 30

12147H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2732.65	Opsumit [JC]

■ RIOCIQUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be aged 18 years or older.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

CARDIOVASCULAR SYSTEM

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

riociguat 2 mg tablet, 84

11013P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

riociguat 1.5 mg tablet, 42

10989J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 500 microgram tablet, 84

10995Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

riociguat 2 mg tablet, 42

10984D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 500 microgram tablet, 42

11001B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 2.5 mg tablet, 42

11002C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 1 mg tablet, 42

10976Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 2.5 mg tablet, 84

11019Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

riociguat 1.5 mg tablet, 84

10977R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

riociguat 1 mg tablet, 84

11020B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3435.42	Adempas [BN]

■ RIOCIQUAT

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 number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

riociguat 500 microgram tablet, 42

11040C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 1 mg tablet, 42

11054T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

▪ **RIOCIGUAT**

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

- 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 following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

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.
- The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

riociguat 2 mg tablet, 84

11039B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3435.42	Adempas [BN]

riociguat 1.5 mg tablet, 42

11047K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 500 microgram tablet, 84

11059C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3435.42	Adempas [BN]

riociguat 2 mg tablet, 42

11038Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 2.5 mg tablet, 42

11057Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]

riociguat 2.5 mg tablet, 84

11024F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3435.42	Adempas [BN]

riociguat 1.5 mg tablet, 84

11048L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3435.42	Adempas [BN]

riociguat 1 mg tablet, 84

11053R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3435.42	Adempas [BN]

SELEXIPAG

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Special Pricing Arrangements apply.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

selexipag 800 microgram tablet, 60

12266N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3450.00	Upravi [JC]

SELEXIPAG

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

(i) Hospitalisation due to worsening PAH;

(ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;

(iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;

(iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;

(v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note 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.

selexipag 200 microgram tablet, 140

12258E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8050.00	Upravi [JC]

SELEXIPAG

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR

- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Transitioning from non-PBS subsidised to PBS-subsidised supply - 'Grandfather' treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug prior to 1 February 2021, **AND**
- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, prior to treatment initiation with this drug, **AND**
- Patient must have had WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have had WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
 - BMPR2 mutation
 - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
 - Other mutations
- Drugs and toxins induced PAH

- PAH associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis

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.

selexipag 1.4 mg tablet, 60

12240F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 400 microgram tablet, 60

12235Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 1.6 mg tablet, 60

12265M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12252W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 1 mg tablet, 60

12259F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 600 microgram tablet, 60

12263K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 800 microgram tablet, 60

12249Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

selexipag 200 microgram tablet, 60

12247N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

▪ **SILDENAFIL**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- 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
- 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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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	..	169.35	^a APO-Sildenafil PHT [TX] ^a SILDATIO PHT [RW] ^a Sildenafil PHT APOTEX [TY]	^a Revatio [UJ] ^a Sildenafil AN PHT 20 [EA] ^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.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, but only for 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.

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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**

- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

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Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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. EST Monday to Friday).

sildenafil 20 mg tablet, 90

12144E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.35	^a APO-Sildenafil PHT [TX] ^a SILDATIO PHT [RW] ^a Sildenafil PHT APOTEX [TY]	^a Revatio [UJ] ^a Sildenafil AN PHT 20 [EA] ^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 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Clinical criteria:

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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.

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.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and 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. EST Monday to Friday).

tadalafil 20 mg tablet, 56

1308W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	475.54	^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.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (starting dual therapy in an untreated patient for the first time)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, but only for 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.

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.

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.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Where it is not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC cannot be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

The test results provided must not be more than 2 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (starting dual therapy in a treated patient for the first time)

Clinical criteria:

- The condition must be PAH of WHO Functional Class III severity at the time dual therapy is initiated; OR
- The condition must be PAH of WHO Functional Class IV severity at the time dual therapy is initiated, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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. EST Monday to Friday).

Note Where a patient has had one PAH agent PBS-subsidised and the other non-PBS-subsidised, apply under this 'Initial 2' restriction type for each agent individually. Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (dual therapy - change)

Clinical criteria:

- Patient must have received PBS-subsidised dual combination therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy, (iii) 'Grandfather' treatment for dual therapy, with at least one agent in the combination changing, **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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

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. EST Monday to Friday).

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (dual therapy)

Clinical criteria:

- Patient must have received PBS-subsidised dual therapy through one of the following treatment phase restrictions: (i) Initial 1 for dual therapy, (ii) Initial 2 for dual therapy (iii) 'Grandfathered' treatment for dual therapy, with this agent in the combination remaining unchanged from the most recent PBS-subsidised supply, **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.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

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. EST Monday to Friday).

Note If this authority application is to continue dual therapy, but with a change in at least one agent, apply under the 'Initial 3 (dual therapy - change)' treatment phase restriction.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: 'Grandfathered' patient (dual therapy) - transitioning from non-PBS subsidised to PBS-subsidised dual therapy where each PAH agent has been non-PBS subsidised

Clinical criteria:

- Patient must have been receiving non-PBS-subsidised dual therapy with PAH agents consisting of a phosphodiesterase-5 inhibitor combined with a prostanoid, where each agent was non-PBS-subsidised, prior to 1 March 2021, **AND**
- The condition must be PAH that was of WHO Functional Class III severity at the time dual therapy was initiated; OR
- The condition must be PAH that was of WHO Functional Class IV severity at the time dual therapy was initiated, **AND**

- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies if non-PBS-subsidised dual therapy was initiated for WHO Functional Class III/IV PAH: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in an untreated patient with Class IV disease severity; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor, where non-PBS subsidised prostanoid-PDE-5i dual therapy was initiated in a patient with Class III/IV disease severity that had been treated with at least endothelin receptor/phosphodiesterase-5 inhibitor/prostanoid monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost.

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.

Applications for authorisation must be lodged either electronically or via mail/postal service and include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension Initial Grandfather dual therapy authority application form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Where it was not possible to perform all 3 tests on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC could not be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests were able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

Where a RHC could not be performed on clinical grounds, confirmation of the reason(s) must be provided with the authority application by a second PAH physician or cardiologist with expertise in the management of PAH.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria for dual therapy for this condition.

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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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. EST Monday to Friday).

tadalafil 20 mg tablet, 56

12151M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	475.54	^a Adcirca [LY] ^a TADALIS 20 [LR]	^a Tadalca [CR]

■ DERMATOLOGICALS

■ ANTIPSORIATICS

ANTIPSORIATICS FOR SYSTEMIC USE

Psoralens for systemic use

■ METHOXSALLEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority required (STREAMLINED)

10988

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

Treatment criteria:

- Must be treated by a haematologist; OR

- Must be treated by a medical physician working under the supervision of a haematologist.
- A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12154Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.08	5	..	*208.94	Uvadex [TQ]

■ METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority required (STREAMLINED)**10985**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Population criteria:

- Patient must be aged 18 years or over.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12156T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	6	..	*417.88	Uvadex [TQ]

■ OTHER DERMATOLOGICAL PREPARATIONS**OTHER DERMATOLOGICAL PREPARATIONS***Agents for dermatitis, excluding corticosteroids***■ 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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
 All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**

- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **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 greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old, **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, **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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break..

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; or
 - (iv) the IgE result; and
 - (v) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - 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
 - the details of prior biological medicine treatment including the details of date and duration of treatment; and
 - eosinophil count and date; and
 - the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or
 - the IgE results; and
 - the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12293B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1609.86	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab

(see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note 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.servicesaustralia.gov.au or 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. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma adolescent and adult continuing PBS authority application form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) a completed Asthma Control Questionnaire (ACQ-5) score.

Authority required

Uncontrolled severe asthma

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or 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 condition prior to 1 April 2021, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- 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 a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have had a documented blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented total serum human immunoglobulin E greater than or equal to 30 IU/mL measured no more than 12 months prior to initiating a biological medicine, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating a biological medicine for this condition, **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 commencement of a biological medicine treatment for severe asthma, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine, **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 a biological medicine for this condition, **AND**
- Patient must not receive more than 24 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 with optimised asthma therapy and must be declared to have been met at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; **AND**

- (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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.

An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma dupilumab initial grandfather PBS authority application form which seeks details of the following (if not already provided):
 - (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) a eosinophil pathology report (eosinophil counts and dates) prior to initiating a biological medicine for this condition; or
 - (iii) IgE results prior to initiating a biological medicine for this condition; and
 - (iv) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose; and
 - (v) Date of commencing non-PBS-subsidised treatment with this drug.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12302L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1609.86	Dupilent [SW]

■ DUPILUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE 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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; or
 - (iv) the IgE result; and
 - (v) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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 greater than or equal to 30 IU/mL with a past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE 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.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:
 - (i) 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
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
 - (iii) eosinophil count and date; and
 - (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or
 - (v) the IgE results; and
 - (vi) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12309W	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1609.86	Dupixent [SW]

■ 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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note 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.servicesaustralia.gov.au or 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. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma adolescent and adult continuing PBS authority application form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) a completed Asthma Control Questionnaire (ACQ-5) score.

Authority required

Uncontrolled severe asthma

Treatment Phase: Grandfather treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or 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 condition prior to 1 April 2021, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- 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 a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have had a documented blood eosinophil count greater than or equal to 300 cells per microlitre measured no more than 12 months prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids, measured no more than 12 months prior to initiating a biological medicine for this condition; OR
- Patient must have had a documented total serum human immunoglobulin E greater than or equal to 30 IU/mL measured no more than 12 months prior to initiating a biological medicine, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating a biological medicine for this condition, **AND**

- Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine, **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 a biological medicine for this condition, **AND**
- Patient must not receive more than 24 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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 with optimised asthma therapy and must be declared to have been met at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; **AND**
- (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, 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.

An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

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.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Uncontrolled severe asthma dupilumab initial grandfather PBS authority application form which seeks details of the following (if not already provided):
 - (i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) a eosinophil pathology report (eosinophil counts and dates) prior to initiating a biological medicine for this condition; or
 - (iii) IgE results prior to initiating a biological medicine for this condition; and
 - (iv) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose; and
 - (v) Date of commencing non-PBS-subsidised treatment with this drug.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12318H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1609.86	Dupixent [SW]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Other anterior pituitary lobe hormones and analogues

■ PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

11177G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*557.16	Somavert [PF]

■ PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**

- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) two completed authority prescription forms ; and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11181L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11179J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11173C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4178.57	Somavert [PF]

HYPOTHALAMIC HORMONES

Somatostatin and analogues

■ LANREOTIDE

Authority required (STREAMLINED)**7025**

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)**4575**

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

5777C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2184.96	Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

5779E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3638.88	Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

5778D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2907.86	Somatuline Autogel [IS]

■ LANREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)**10061**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11513Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3638.88	Somatuline Autogel [IS]

■ OCTREOTIDE

Authority required (STREAMLINED)

8161

Acromegaly

Clinical criteria:

- The condition must be controlled with octreotide immediate release injections, **AND**
 - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
 - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
 - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

5901

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

5906

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10533J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3479.62	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10543X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2613.72	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10550G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3998.62	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

■ OCTREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10061

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11893Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3998.62	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

■ OCTREOTIDE

Authority required (STREAMLINED)

8165

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
 - Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
 - The treatment must be after failure of other therapy including dopamine agonists; OR
 - The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
 - The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
 - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
 - The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
 - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)**6390**

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)**6369**

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

9508K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*619.02	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.05 [NV]

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

9510M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6194.52	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.5 [NV]

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

9509L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1236.42	^a Octreotide GH [HQ] ^a Octreotide (SUN) [RA]	^a Octreotide MaxRx [GQ] ^a Sandostatin 0.1 [NV]

■ PASIREOTIDE EMBONATE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**

- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) a completed authority prescription form; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

d) a recent result of GH or IGF-1 levels must be provided.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10882R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [RJ]

pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10886Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [RJ]

pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10883T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [RJ]

■ **CALCIUM HOMEOSTASIS****ANTI-PARATHYROID AGENTS***Other anti-parathyroid agents*■ **CINACALCET**

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required (STREAMLINED)**10067**

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

cinacalcet 60 mg tablet, 28

11886N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*129.28	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

11885M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*193.92	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 30 mg tablet, 28

11887P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*64.64	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

■ **CINACALCET**

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Authority required

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

- Patient must have failed to respond to conventional therapy, **AND**

- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR

- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

cinacalcet 60 mg tablet, 28

5622X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*129.28	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

5623Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*193.92	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

cinacalcet 30 mg tablet, 28

5621W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*64.64	^a Cinacalcet Mylan [AF]	^a Pharmacor Cinacalcet [CR]

■ **ANTIINFECTIVES FOR SYSTEMIC USE**

■ **ANTIBACTERIALS FOR SYSTEMIC USE**

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

■ **AZITHROMYCIN**

Authority required (STREAMLINED)

6356

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

5616N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*110.76	Zithromax [PF]

■ **ANTIMYCOBACTERIALS**

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

■ **RIFABUTIN**

Authority required (STREAMLINED)

6350

Mycobacterium avium complex infection

Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

Authority required (STREAMLINED)

6356

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

rifabutin 150 mg capsule, 30

9541E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*525.84	Mycobutin [PF]

■ **ANTIVIRALS FOR SYSTEMIC USE**

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

■ **GANCICLOVIR**

Authority required (STREAMLINED)

4972

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

4999

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

5749N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*232.18	^a Cymevene [PB]	^a GANCICLOVIR SXP [XC]

■ VALACICLOVIR

Authority required (STREAMLINED)

5975

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

9568N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*221.00	^a APO-Valaciclovir [TX] ^a Valaciclovir APOTEX [GX]	^a APX-Valaciclovir [TY] ^a Valaciclovir RBX [RA]
			^B 14.90	*235.90	^a Valtrex [RW]	

■ VALGANCICLOVIR

Authority required (STREAMLINED)

4989

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

9569P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1095.54	^a VALGANCICLOVIR HETERO [GG] ^a Valganciclovir Sandoz [SZ]	^a Valganciclovir Mylan [AF]

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9655E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*4346.10	Valcyte [RO]

Antivirals for treatment of HCV infections

■ GLECAPREVIR + PIBRENTASVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11332K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	18666.67	Maviret [VE]

NP

■ GLECAPREVIR + PIBRENTASVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
 - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
 - The treatment must be limited to a maximum duration of 16 weeks.
- The application must include details of the prior treatment regimen containing an NS5A inhibitor.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11333L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	3	..	18666.67	Maviret [VE]

▪ GLECAPREVIR + PIBRENTASVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

11345D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	18666.67	Maviret [VE]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10661D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11875.00	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10667K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	1	..	11875.00	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10669M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	5	..	11875.00	Harvoni [GI]

■ **RIBAVIRIN**

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 100

12786Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	2	..	*950.00	Ibavir [IX]

■ **SOFOSBUVIR + VELPATASVIR**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11145N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	12500.00	Eplclusa [GI]

■ **SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11665Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	12500.00	Vosevi [GI]

■ **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**■ **ANTINEOPLASTIC AGENTS****ANTIMETABOLITES***Pyrimidine analogues*

■ AZACITIDINE

Note 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.

Authority required

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

12771E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*1345.96	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

■ AZACITIDINE

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).
Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
 - 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
 - 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
 - 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
 - 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
 - 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
 - Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- a copy of the full blood examination report; and
- a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

9597D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*1345.96	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

▪ **AZACITIDINE**

Note 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. EST Monday to Friday).

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

9598E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*1345.96	^a Azacitidine Accord [OC] ^a Azacitidine Juno [JO] ^a Azadine [RZ]	^a AZACITIDINE DR.REDDY'S [RI] ^a Azacitidine-Teva [TB]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

■ DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority required (STREAMLINED)

6234

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

Authority required (STREAMLINED)

6274

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial

5705G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*893.76	^a Caelyx [BX]	^a Liposomal Doxorubicin SUN [RA]

PROTEIN KINASE INHIBITORS

Other protein kinase inhibitors

■ MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

11505M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	20413.00	Rydapt [NV]

■ MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

midostaurin 25 mg capsule, 112

11552B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	20413.00	Rydapt [NV]

■ MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition; OR
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;

- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 56

11553C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	10206.50	Rydapt [NV]

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

■ RITUXIMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).
Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

rituximab 500 mg/50 mL injection, 50 mL vial

12739L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	540.43	^a Riximyo [SZ]	^a Truxima [EW]

■ RITUXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of

rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9446

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

rituximab 500 mg/50 mL injection, 50 mL vial

11805H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*1080.86	^a Riximyo [SZ]	^a Truxima [EW]

■ RITUXIMAB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)

- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Authority required (STREAMLINED)

9336

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

Authority required (STREAMLINED)

9539

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

11813R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*648.51	^a Riximyo [SZ]	^a Truxima [EW]

rituximab 500 mg/50 mL injection, 50 mL vial

11800C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	..	..	*2161.72	^a Riximyo [SZ]	^a Truxima [EW]

▪ RITUXIMAB

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.
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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active microscopic polyangiitis
Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.
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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**

- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
- Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10591K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	216.17	^a Riximyo [SZ]	^a Truxima [EW]

rituximab 500 mg/50 mL injection, 50 mL vial

10593M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	540.43	^a Riximyo [SZ]	^a Truxima [EW]

■ RITUXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of

the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of

the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient whose most recent course of PBS-subsidised therapy was with this drug and whose response to this treatment is demonstrated at 12 weeks, may apply for a further course of this drug under the First continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to this drug and who qualifies to trial an alternate biological medicine according to the interchangeability arrangements for biological medicines for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 2 infusions of this drug under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this drug provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with this drug. The demonstration of response must be submitted within 4 weeks of assessment.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

rituximab 500 mg/50 mL injection, 50 mL vial

9544H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	540.43	^a Riximyo [SZ]	^a Truxima [EW]

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**

- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)
6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)
6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)
6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)
6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)
6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)
6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5829T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*247.68	Nivestim [PF]

■ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes and filgrastim 300 microgram/mL injection, 10 x 1 mL vials are equivalent for the purposes of substitution.

Authority required (STREAMLINED)
7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)
6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)
6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)
6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)
6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)
6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)
6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

5741E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*619.20	^a Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*345.08	^a Zarzio [SZ]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	11	..	*345.08	^a Neupogen [AN]	^a Nivestim [PF]

■ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*553.16	^a Zarzio [SZ]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

5743G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*553.18	^a Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	11	..	*553.16	^a Neupogen [AN]	^a Nivestim [PF]

■ LIPEGFILGRASTIM
Authority required (STREAMLINED)
7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10936N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1175.00	Lonquex [TB]

■ PEGFILGRASTIM
Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Pelgraz or Ziextenzo is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Authority required (STREAMLINED)
7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)
7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	346.39	^a Neulasta [JU]	^a Pelgraz [OC]
					^a Ristempa [JO]	^a Tezmota [JX]
					^a Ziextenzo [SZ]	

Interferons
■ INTERFERON GAMMA-1B
Authority required (STREAMLINED)
6222

Chronic granulomatous disease

Clinical criteria:

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

5769P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*2210.80	Imukin [LM]

PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required (STREAMLINED)
5004

Chronic hepatitis C infection

Treatment criteria:

- Must be treated in an accredited treatment centre.

Population criteria:

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Clinical criteria:

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

9516W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1218.58	Pegasys [RO]

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

9515T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1052.24	Pegasys [RO]

Other immunostimulants
PLERIXAFOR

Note Special Pricing Arrangements apply.

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

Authority required (STREAMLINED)
4549

Mobilisation of haematopoietic stem cells

Clinical criteria:

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

10083Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	6641.45	Mozobil [GZ]

■ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

■ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 5 repeats will be authorised.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

- Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.
This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

12756J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	266.34	Orencia [BQ]

ABATACEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of

rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

abatacept 250 mg injection, 1 vial

5605B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	266.34	Orencia [BQ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6847

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10232M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*32472.90	Lemtrada [GZ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7714

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10228H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*54121.50	Lemtrada [GZ]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10190H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5640.63	Soliris [XI]

▪ **ECULIZUMAB**

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**

- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

- presence of schistocytes on blood film;
- low or absent haptoglobin;
- lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
 - a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
 - a sCr of greater than the age-appropriate ULN in paediatric patients; or
 - a renal biopsy consistent with aHUS;
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and
- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10191J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5640.63	Soliris [XI]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Note **WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

- An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- an eGFR within +/- 25% from baseline; or
- an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- A completed authority prescription form; and
- A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
- A detailed cover letter from the prescriber; and
- A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- A measurement of body weight at the time of application; and
- An identified genetic mutation, if applicable; and
- A family history of aHUS, if applicable; and

- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10525Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	5640.63	Soliris [XI]

■ ECULIZUMAB

- Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
- Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
- Active malignancy;
 - Active HIV infection;
 - Hematopoietic stem cell transplants;
 - Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
 - Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
 - Active autoimmune diseases;
- In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.
- Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
- Presenting clinical features, including history, acute treatment and medications;
 - Results of testing for genetic mutations (if available);
 - Family history of aHUS, especially in first-degree relatives;
 - Patient's prior history of episodes of active and progressing TMA caused by aHUS;
 - Exclusion of alternative causes of TMA;
 - History of renal or other organ transplant (if any);
 - Any other matters considered relevant by the prescriber.
- In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.
- Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.
- A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10⁹/L);OR(iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
 - (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
 - (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application, and
- (7) An identified genetic mutation, if applicable; and
- (8) A family history of aHUS if applicable; and
- (9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
- (10) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (11) An inclusion of the individual consequences of recurrent disease; and
- (12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and

- (6) An identified genetic mutation, if applicable; and
(7) A family history of aHUS, if applicable; and
(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
(9) A history of kidney transplant if applicable (especially if required due to aHUS); and
(10) An inclusion of the individual consequences of recurrent disease, if applicable; and
(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
- This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10183Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5640.63	Soliris [XI]

■ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5554

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*2301.12	^a Certican [NV]	^a Everocan [CR]

everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*383.52	^a Certican [NV]	^a Everocan [CR]

everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*767.04	^a Certican [NV]	^a Everocan [CR]

everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*3068.16	^a Certican [NV]	^a Everocan [CR]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5554

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

9500B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*489.02	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

9502D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*263.76	^a APO-Mycophenolate [TX] ^a Ceptolate [AF] ^a Mycophenolate APOTEX [GX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a MycoCept [RF] ^a Mycophenolate GH [GQ] ^a Pharmacor Mycophenolate 500 [CR]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority required (STREAMLINED)

4084

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

4095

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

Clinical criteria:

- The condition must be proven by biopsy.

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

mycophenolate 180 mg enteric tablet, 120

9503E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*171.58	Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

9504F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*343.12	Myfortic [NV]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Note For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution

Authority required (STREAMLINED)

5653

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5600

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 250 mg capsule, 100

9501C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*263.88	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

mycophenolate mofetil 250 mg capsule, 50

1839T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*263.88	^a Ceptolate [AF]

■ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required (STREAMLINED)

9818

Clinically definite relapsing-remitting multiple sclerosis

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9505G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1268.34	Tysabri [BD]

■ OCRELIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7699

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

7386

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11242Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*17533.00	Ocrevus [RO]

■ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

sirolimus 2 mg tablet, 100

9548M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2350.12	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

9550P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*924.02	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9747B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*587.54	Rapamune [PF]

sirolimus 1 mg tablet, 100

9549N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1175.04	Rapamune [PF]

▪ VEDOLIZUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- 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).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be

authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Special Pricing Arrangements apply.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 Crohn disease

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, **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.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
 - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
 - (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10390W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2949.93	Entyvio [TK]

▪ **VEDOLIZUMAB**

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).
From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.
A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.
A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.
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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

- Patient must be aged 18 years or older.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment, **AND**
- Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10384M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2949.93	Entyvio [TK]

Tumor necrosis factor alpha (TNF-alpha) inhibitors

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

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)

11526

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12348X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12417M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*818.54	Amgevita [AN]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12355G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

ADALIMUMAB

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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12698H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12696F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

■ ADALIMUMAB

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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12733E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12697G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021,

AND

- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listing is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12695E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*818.54	^a Amgevita [AN]

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12699J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9662M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12431G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for 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:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis
Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9663N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	818.54	^a Amgevita [AN] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12444Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

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HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz or Idacio is encouraged for treatment naive patients. 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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note 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. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12435L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*818.54	^a Amgevita [AN]

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12406Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	818.54	^a Humira [VE]

■ ETANERCEPT

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommendation authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be under 18 years of age.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and etanercept for a patient who has severe active juvenile idiopathic arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

etanercept 50 mg/mL injection, 4 x 1 mL syringes

12675D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

12735G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

12740M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	469.63	Enbrel [PF]

■ ETANERCEPT

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL syringes

5733R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

5735W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	939.25	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

5734T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	469.63	Enbrel [PF]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one

time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6.

A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of the most recent clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

infliximab 100 mg injection, 1 vial

11389K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they

continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11424G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB
Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a

treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements. (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

infliximab 100 mg injection, 1 vial

11448M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months). Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within

these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

infliximab 100 mg injection, 1 vial

11481G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4524

Acute severe ulcerative colitis

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10067W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*1603.55	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [OQ]	

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.
(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

12069

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11400B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

▪ **INFLIXIMAB**

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
 - a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
 - a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
 - a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn

disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatal of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9668

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11449N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9481

Ankylosing spondylitis

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 ankylosing spondylitis.

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 aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11486M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	3	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in

biological medicine therapy of less than 5 years); or

(iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11459D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active 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) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines.

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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11497D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF]	^a Remicade [JC]
					^a Renflexis [OQ]	

■ INFLIXIMAB**Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having

to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they

continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF- α antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12075

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The 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.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

infliximab 100 mg injection, 1 vial

11490R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*962.13	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify for initial treatment with respect to the indices of disease severity.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

9787

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11423F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines. 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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

9188

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11514B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis

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 ankylosing spondylitis.

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 aged 18 years or older.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

11482H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11606W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-

subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing

treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

12042

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11461F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline

PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

8844

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required (STREAMLINED)

8940

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11605T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*1603.55	^a Inflectra [PF]	^a Renflexis [OQ]

▪ **INFLIXIMAB**

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided.

If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - critical shortage of tocilizumab' PBS listing.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - Critical shortage of tocilizumab - Temporary listing

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab),

AND

- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis.

This PBS listings is a temporary listing and may only be used when an application for initial supply of this medicine has been made under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab).

infliximab 100 mg injection, 1 vial

12717H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab, tofacitinib and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab, tofacitinib or vedolizumab at any one time.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, golimumab, infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the Janus kinase (JAK) inhibitor (tofacitinib).

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to start their first cycle as of 1 July 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. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

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 after 1 July 2021.

(1) Initial treatment.

Applications for initial treatment should be made where:

- an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- an adult 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 agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
- an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and tofacitinib, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab or infliximab subcutaneous form or vedolizumab subcutaneous form, a minimum of 8 weeks for tofacitinib, and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab intravenous form or vedolizumab intravenous form.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Vedolizumab subcutaneous form only:

Initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8

weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(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 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.

Adalimumab and infliximab 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between the intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course (except tofacitinib) will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

(4) 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 medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR

- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

10196P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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 with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR

- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5754W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB
Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreat of conventional therapies is not required.

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and
- (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:
 - (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
 - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

infliximab 100 mg injection, 1 vial

5755X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

INFLIXIMAB
Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or

continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

9654D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).
 - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
- Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course. Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide from weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised

TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5757B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 8 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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.

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.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab and upadacitinib.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or 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 agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

Grandfather patients (upadacitinib only)

A patient who commenced treatment with upadacitinib for ankylosing spondylitis prior to 1 October 2021 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(b) 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.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with 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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

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.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) 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 medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
 - (ii) a completed BASDAI Assessment Form; and
 - (iii) a completed Exercise Program Self Certification Form included in the supporting information form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:

- (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a completed BASDAI Assessment Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5753T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib, upadacitinib 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 receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the 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.

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. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single 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 [further details are under '(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy' below].

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 active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for guselkumab or ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

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.

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 and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction 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 drug within the same treatment cycle.

Within a 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 3 times in this treatment cycle with biological medicines.

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.

(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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction

and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5756Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, 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, 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, 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 and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of

at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

- (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
 - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
 - (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.
- The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5758C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	320.71	^a Inflectra [PF] ^a Renflexis [OQ]	^a Remicade [JC]

Interleukin inhibitors

■ ANAKINRA

Note This drug is not PBS-subsidised for conditions other than CAPS.

Authority required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

10264F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1410.75	Kineret [ZO]

■ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.
The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 200 mg/10 mL injection, 10 mL vial

12791F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

12775J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12763R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

tocilizumab 200 mg/10 mL injection, 10 mL vial

12796L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

12794J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12802T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months); or
- (iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months).
- (iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of

treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 200 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 200 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; **OR**
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of

methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
- (ii) details of prior treatment including dose and duration of treatment;
- (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Complex Drugs
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HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

12706R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1161.61	^a RoActemra [DZ]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1481Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	^a Actemra [RO]

tocilizumab 200 mg/10 mL injection, 4 x 10 mL vials

12692B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*1161.61	^a RoActemra [DZ]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of

less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient 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.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

10056G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10077J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10064Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

10058J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10081N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10072D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (SJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised

tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 400 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 400 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retiral or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 400 mg/20 mL injection, 4 x 20 mL vials

12707T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*2259.08	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12694D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2259.08	^a RoActemra [DZ]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1482B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	^a Actemra [RO]

■ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (SJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retreat or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count), except if the patient has had a break in therapy of more than 12 months.

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 approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain an adequate response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle.

Assessment of response according to these revised baseline measurements may then occur. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used to assess response to the second course.

(5) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 3 treatment restriction.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Pharmaceutical benefits that have the brand Actemra 80 mg injection in a pack size of 1 and pharmaceutical benefits that have the brand RoActemra 80 mg injection in a pack size of 1 or a pack size of 4 are equivalent for the purposes of substitution in the case of a shortage.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
 - (ii) details of prior treatment including dose and duration of treatment;
 - (iii) pathology reports detailing CRP and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or
- (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive

movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR

- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note 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. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

12713D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	501.28	^a RoActemra [DZ]

tocilizumab 80 mg/4 mL injection, 4 mL vial

1476Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	^a Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 x 4 mL vials

12714E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.25	..	..	*501.28	^a RoActemra [DZ]

■ TOCILIZUMAB
Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 24 months).
- (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months) Initial applications for a new patient (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab (either treatment with infliximab intravenous (IV) form alone or a combination of IV and subcutaneous form) and 2 infusions of rituximab.

Patients must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy, and this assessment must be conducted no later than 4 weeks from the completion of that course.

Where a response assessment is not provided with subsequent applications, 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.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. Two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats.

The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide form weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Rituximab patients:

Subsequent applications may be submitted to Services Australia with new baselines if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Adalimumab and Infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Infliximab patients:

A patient may swap between the intravenous form and subcutaneous form of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) 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. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

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 agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

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.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where 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. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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:
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HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 200 mg/10 mL injection, 10 mL vial

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment.

Applications for initial treatment should be made where:

- a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
- a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - 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
- a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
- 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).

From 1 September 2017, a patient must be assessed for response to any course of initial PBS-subsidised treatment

following a minimum of 12 weeks of therapy and no later than 4 weeks from the date that course was ceased for adalimumab or infliximab subcutaneous form or ustekinumab or vedolizumab subcutaneous form, and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab intravenous form or vedolizumab intravenous form. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab subcutaneous form only:

Initial treatment to subcutaneous form of infliximab should be permitted after administration of at least 2 initial intravenous infusions of infliximab. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

Vedolizumab subcutaneous form only: initial treatment to subcutaneous form of vedolizumab should be permitted after administration of at least 2 of the 3 initial intravenous infusions of vedolizumab. Where two initial doses of vedolizumab (at weeks 0 and 2) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. A maximum quantity and number of repeats to provide for weeks 6, 8, 10, 12, 14 and 16 will be authorised. Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity to provide for weeks 14 and 16 will be authorised.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab patients:

A patient may swap between the intravenous and subcutaneous forms of infliximab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with infliximab.

Vedolizumab patients:

A patient may swap between intravenous and subcutaneous forms of vedolizumab at any time under the continuing treatment restrictions provided the patient has demonstrated adequate response to treatment with vedolizumab.

Adalimumab and infliximab intravenous form only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

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 once within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that

biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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:
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Complex Drugs
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HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Population criteria:

- Patient must be aged 18 years or older.

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment; and
- (iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and

submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

AND

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
 - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and

submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11182M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*15236.32	Stelara [JC]

Calcineurin inhibitors

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6628

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5631J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	54.10	Sandimmun [NV]

■ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6643

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)

6676

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a dermatologist.

Authority required (STREAMLINED)

6631

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**

- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)
6638

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
2	5	..	*74.40	Neoral 10 [NV]

ciclosporin 50 mg capsule, 30

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*268.16	^a APO-Ciclosporin [TX] ^a Neoral 50 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 25 mg capsule, 30

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*128.88	^a APO-Ciclosporin [TX] ^a Neoral 25 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 100 mg/mL oral liquid, 50 mL

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
4	5	..	*1263.16	Neoral [NV]

ciclosporin 100 mg capsule, 30

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*546.40	^a APO-Ciclosporin [TX] ^a Neoral 100 [NV]	^a Cyclosporin Sandoz [SZ]

■ TACROLIMUS
Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)
5569

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 2 mg capsule, 100

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
2	5	..	*1000.00	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
2	3	..	*658.20	ADVAGRAF XL [LQ]

tacrolimus 750 microgram capsule, 100

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
2	5	..	*375.00	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*438.80	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 1 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule, 100

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*219.40	^a Pacrolim [AF] ^a Prograf [LL]	^a Pharmacor Tacrolimus 0.5 [CR] ^a Tacrograf [RW]

^a TACROLIMUS APOTEX [TX]

^a Tacrolimus Sandoz [SZ]

tacrolimus 5 mg capsule, 50

9561F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1096.44	^a Pacrolim [AF] ^a Prograf [LL] ^a TACROLIMUS APOTEX [TX]	^a Pharmacor Tacrolimus 5 [CR] ^a Tacrograf [RW] ^a Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9666R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*750.44	ADVAGRAF XL [LQ]

tacrolimus 500 microgram modified release capsule, 30

9664P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*75.04	ADVAGRAF XL [LQ]

tacrolimus 1 mg modified release capsule, 60

9665Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*263.28	ADVAGRAF XL [LQ]

Other immunosuppressants
■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's medical records.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12061T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4704.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12034J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4495.22	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12026Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12059Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	5928.74	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

lenalidomide 10 mg capsule, 21

12057N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4704.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

12039P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	4495.22	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

12062W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

12036L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	5928.74	Revlimid [CJ]

■ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR

2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
- (g) a signed patient acknowledgement 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
- (iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note 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. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

2802L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4704.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

2799H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	4495.22	Revlimid [CJ]

LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**

- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4704.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4495.22	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5928.74	Revlimid [CJ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and ineligibility for prior stem cell transplant; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgement.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (lenalidomide and dexamethasone), or, in patients initiated on triple therapy (lenalidomide, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously been authorised with a PBS prescription with this drug for the condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4704.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4495.22	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5486.60	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5928.74	Revlimid [CJ]

■ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the date the autologous stem cell transplant was performed, and nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the results of current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

- (c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have demonstrated progressive disease, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 5 mg capsule, 28

11967W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	5993.62	Revlimid [CJ]

lenalidomide 10 mg capsule, 28

11968X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6272.56	Revlimid [CJ]

lenalidomide 15 mg capsule, 28

11964Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	7315.46	Revlimid [CJ]

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be declared to be held on the patient's medical records.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 15 mg capsule, 14

12012F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3657.73	Revlimid [CJ]

lenalidomide 25 mg capsule, 14

12019N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3952.49	Revlimid [CJ]

lenalidomide 5 mg capsule, 14

12035K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	2996.81	Revlimid [CJ]

lenalidomide 10 mg capsule, 14

12070G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3136.28	Revlimid [CJ]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
 - The treatment must be in combination with bortezomib and dexamethasone, **AND**
 - Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
 - Patient must have undergone or be ineligible for a stem cell transplant, **AND**
 - Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

pomalidomide 3 mg capsule, 14

12666P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6650.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12665N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6650.00	Pomalyst [CJ]

■ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

If treatment with either bortezomib or lenalidomide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to either bortezomib or lenalidomide treatment develops during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide; and
- (4) reports demonstrating the patient has failed treatment with, providing details of the contraindication to or details of the nature and severity of the intolerance to bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
 - Patient must not have progressive disease, **AND**
 - The treatment must be in combination with dexamethasone, **AND**
 - Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

MUSCULO-SKELETAL SYSTEM

- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
10406Q	1	..	9975.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
10387Q	1	..	9975.00	Pomalyst [CJ]

■ THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required (STREAMLINED)

5914

Multiple myeloma

thalidomide 50 mg capsule, 28

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9566L	4	..	*1364.60	Thalomid [CJ]

thalidomide 100 mg capsule, 28

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9667T	2	..	*1364.58	Thalomid [CJ]

■ MUSCULO-SKELETAL SYSTEM

■ MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

■ BACLOFEN

Authority required (STREAMLINED)

7152

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

7134

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

7153

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)

7148

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11195F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*766.24	Sintetica Baclofen Intrathecal [BZ]

■ **BACLOFEN**

Note Pharmaceutical benefits that have the forms baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules and baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6925

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

6939

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

6940

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)

6911

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11126N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	958.00	^a Sintetica Baclofen Intrathecal [BZ]

baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

11421D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*958.00	^a Bacthecal [DZ]

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

5617P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*958.00	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ **DRUGS FOR TREATMENT OF BONE DISEASES**

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

■ IBANDRONATE

Authority required (STREAMLINED)**5291**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

ibandronate 6 mg/6 mL injection, 6 mL vial

5750P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	291.86	Bondronat [IX]

■ PAMIDRONATE DISODIUM

Authority required (STREAMLINED)**4433**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

5669J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	55.26	Pamisol [PF]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

5668H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*55.26	Pamisol [PF]

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

5667G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*55.24	Pamisol [PF]

■ PAMIDRONATE DISODIUM

Authority required (STREAMLINED)**4433**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required (STREAMLINED)**5218**

Multiple myeloma

Authority required (STREAMLINED)**5291**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

5670K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	82.89	Pamisol [PF]

■ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**5735**

Multiple myeloma

Authority required (STREAMLINED)**5605**

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority required (STREAMLINED)**5703**

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

Authority required (STREAMLINED)**5704**

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

9653C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	72.80	^a APO-Zoledronic Acid [TX] ^a Zometa [SA]	^a DEZTRON [DZ]

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

Other drugs for disorders of the musculo-skeletal system

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL injection, 5 mL vial

11378W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110000.00	Spinraza [BD]

■ NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- Onset between 6 and 18 months; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Weakness in trunk righting/derotation; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- Onset between 18 months and 3 years of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Application for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - specification of SMA type (I, II or IIIa); and
 - sign(s) and symptom(s) that the patient has experienced; and
 - patient's age at the onset of sign(s) and symptom(s).

nusinersen 12 mg/5 mL injection, 5 mL vial

11363C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]

■ **NUSINERSEN**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
 Applications for 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

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.
- Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

nusinersen 12 mg/5 mL injection, 5 mL vial

12177X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]

■ RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with standard of care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12606L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	12144.72	Evrysdi [RO]

■ RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- Onset between 6 and 18 months; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Weakness in trunk righting/derotation; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- Onset between 18 months and 3 years of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s).

Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Transitioning from non-PBS to PBS subsidised treatment - Grandfather treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2021, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must be responding to non-PBS subsidised risdiplam for this condition at the time of application.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must have been 18 years of age or under at the time non-PBS subsidised treatment with this drug was initiated for this condition.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
 - i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s).

Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
12614X	‡1	..	..	12144.72	Evrysdi [RO]

NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10138

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11913B	4	5	..	*5768.00	Duodopa [VE]

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

10375

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
9743T	8	5	..	*11536.00	Duodopa [VE]

Dopamine agonists

APOMORPHINE

Authority required (STREAMLINED)

10863

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11093W	18	5	..	*7427.34	Apomine Solution for Infusion [PF]

APOMORPHINE

Authority required (STREAMLINED)

11385

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

5610G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8017.20	Movapo [TD]

apomorphine hydrochloride hemihydrate 20 mg/2 mL injection, 5 x 2 mL ampoules

5609F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	72	5	..	*6369.12	Movapo [TD]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

10950H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8017.20	Movapo PFS [TD]

■ APOMORPHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**10863**

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

11477C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2588.00	^a Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

11672H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2588.00	^a Apomine Intermittent [PF]

■ PSYCHOLEPTICS**ANTIPSYCHOTICS***Diazepines, oxazepines, thiazepines and oxepines***■ CLOZAPINE**

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Authority required (STREAMLINED)**5015**

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

11433R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	135.00	Versacloz [PF]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Pfizer ClopineCentral.

Authority required (STREAMLINED)**5015**

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

RESPIRATORY SYSTEM

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

5628F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*64.64	Clopine 25 [PF]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

5626D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*129.28	Clopine 50 [PF]

clozapine 50 mg/mL oral liquid, 100 mL

5630H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.00	Clopine Suspension [PF]

clozapine 100 mg tablet, 100

5629G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*242.38	Clopine 100 [PF]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

5627E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*484.76	Clopine 200 [PF]

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

BENRALIZUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must 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	..	..	3311.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where

they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Continuing PBS Authority Application - Supporting Information Form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) 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	..	3311.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to

an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:

- (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
- (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (iii) the eosinophil count and date; and
- (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:

- (i) 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
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
- (iii) eosinophil count and date; and
- (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

benralizumab 30 mg/mL injection, 1 mL pen device

11994G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	3311.00	Fasenra Pen [AP]

■ 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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab

(see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must 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	..	..	1638.00	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

11839D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1638.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up

to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 at around 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Continuing PBS Authority Application - Supporting Information Form which includes:
 - (i) details of maintenance oral corticosteroid dose; or
 - (ii) 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	..	1638.00	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

10980X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1638.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month

prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count greater than or equal to 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, **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, either daily oral corticosteroids for at least 6 weeks, **OR** a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the eosinophil count and date; and
 - (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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 greater than or equal to 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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:

(i) 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

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(iii) eosinophil count and date; and

(iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

mepolizumab 100 mg/mL injection, 1 mL pen device

12007Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1638.00	Nucala [GK]

mepolizumab 100 mg injection, 1 vial

10996R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1638.00	Nucala [GK]

■ OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR

- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).
- Clinical criteria:**
- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
 - (i) demonstration of failure to achieve an adequate response to standard therapy; and
 - (ii) drug names and doses of standard therapies that the patient has failed; and
 - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 150 mg/mL injection, 1 mL syringe

11176F	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*820.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must 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
	1	..	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11828M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	410.00	Xolair [NV]

■ OMALIZUMAB**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment

with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing restriction may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Balance of supply in a patient aged 6 to 12 years

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11962N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11950Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	410.00	Xolair [NV]

■ OMALIZUMAB

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; OR

- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

11168T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*820.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

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.servicesaustralia.gov.au or 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 Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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: Continuing treatment

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- 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 must be made at around 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 and for the application for 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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 authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and

- (b) a completed Severe Asthma PBS Authority Application and Supporting Information Form which includes details of:
- (i) maintenance oral corticosteroid dose; or
 - (ii) Asthma Control Questionnaire (ACQ-5) score including the date of assessment of the patient's symptoms; or
 - (iii) for patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the exacerbation rate has reduced.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11835X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11824H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	410.00	Xolair [NV]

■ OMALIZUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 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.humanservices.gov.au or 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 allergic asthma
Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR

- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of:
 - (i) maintenance oral corticosteroid dose; and
 - (ii) Asthma Control Questionnaire (ACQ-5) score; or
 - (iii) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11946R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11945Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	410.00	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 benralizumab, dupilumab, mepolizumab and omalizumab for uncontrolled severe asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to benralizumab, dupilumab, mepolizumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under

the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
 - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
 - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 respiratory physician, clinical immunologist, allergist or 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 from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) 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), or (ii) 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, or (iii) 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, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old at the time of application, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **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, **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, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications 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 initial IgE assessment must be no more than 12 months old at the time of 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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Asthma PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

- (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (iii) the IgE result; and
- (iv) 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.servicesaustralia.gov.au or 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 respiratory physician, clinical immunologist, allergist or 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 greater than or equal to 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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Asthma (omalizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:

- (i) 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
- (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and
- (iii) the IgE results; and
- (iv) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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 date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted 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 submitted, 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.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10118M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

10109C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	410.00	Xolair [NV]

■ OMALIZUMAB**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and The Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

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 For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 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.humanservices.gov.au or 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 allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe

asthma in consultation with a respiratory physician, defined by the following standard clinical features: forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability, **AND**

- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **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, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Treatment criteria:

- Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), **AND**

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form, which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the IgE result; and

(iv) Asthma Control Questionnaire (ACQ-5) score; or

(v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10967F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	205.00	Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

10973M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	410.00	Xolair [NV]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

5740

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)

5634

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required (STREAMLINED)

5635

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

5704F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1916.92	Pulmozyme [RO]

MANNITOL

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

7362

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, AND

- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)**7367**

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

mannitol 40 mg powder for inhalation, 280 capsules

2015C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1789.20	Bronchitol [HT]

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

■ IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 12 months or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
 - (3) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
 - (4) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
 - (6) sweat chloride result; and
 - (7) height and weight measurements at the time of application; and
 - (8) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 12 months or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.
- Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem,

erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
 - (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
 - (5) height and weight measurements at the time of application; and
 - (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

ivacaftor 50 mg granules, 56 sachets

11105L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21375.00	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10170G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21375.00	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11098D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21375.00	Kalydeco [VR]

■ LUMACAFITOR + IVACAFITOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.
- The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11465K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	17812.50	Orkambi [VR]

■ LUMACFTOR + IVACFTOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11466L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	17812.50	Orkambi [VR]

■ LUMACAFITOR + IVACAFITOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data in children aged 6 - 11 years and 96 weeks of data in patients aged 12 years and over. Information about the long term benefits of this medicine will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for 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

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis lumacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11866M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	17812.50	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11851R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	17812.50	Orkambi [VR]

■ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note Managed Access Program:

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 48 weeks of data for this medicine and 96 weeks of data for lumacaftor with ivacaftor in children aged 12 years and over. Information about the long term benefits of this medicine and

lumacaftor with ivacaftor will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient being homozygous for the F508del mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11854X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19950.00	Symdeko [VR]

■ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**Note Managed Access Program:**

This medicine has been listed on the PBS via a Managed Access Program (MAP). The Pharmaceutical Benefits Advisory Committee (PBAC) made its recommendation on the basis of 24 weeks of data for tezacaftor with ivacaftor for children aged 12 years and over, as well as on the basis of 96 weeks of data for lumacaftor with ivacaftor in children aged 12 years and over who are homozygous for the F508del mutation. Information about the long term benefits of this medicine and lumacaftor with ivacaftor for patients who are homozygous for the F508del mutation will be collected and analysed under this MAP.

For more information on Managed Access Programs, please visit <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-03/march-2015-other-matters-managed-access-programme-framework>.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be 12 years of age or older.

The patient must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Authority Application Supporting Information Form; and
- (3) a copy of the pathology report detailing the molecular testing for the patient having at least one RF mutation on the CFTR gene; and
- (4) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (5) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (6) height and weight measurements at the time of application; and
- (7) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

For patients who have initiated non-PBS subsidised treatment prior to 1 December 2019, date of initiating treatment, baseline FEV₁ and hospitalisation dates prior to initiating treatment (where available) should be provided.

Authority required

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

For the purposes of this restriction, PBS subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor and tezacaftor/ivacaftor.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis tezacaftor with ivacaftor Continuing Authority Application Supporting Information Form; and
- (3) the result of a FEV₁ measurement performed within a month prior to the date of application. Note: FEV₁ must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV₁ is measured; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and
- (5) height and weight measurements at the time of application; and
- (6) the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 6 months.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11863J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19950.00	Symdeko [VR]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 180 mg tablet, 30

11556F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*1272.18	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 360 mg tablet, 30

11533B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*2544.30	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11499F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*636.12	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

■ DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 250 mg dispersible tablet, 28

11240N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*1187.34	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

11247Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*593.70	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11234G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2374.68	Deferasirox Juno [JU]

■ DEFERASIROX

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 180 mg tablet, 30

11500G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*1272.18	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 360 mg tablet, 30

11536E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2544.30	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11519G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*636.12	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

■ DEFERASIROX

Authority required (STREAMLINED)

8328

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority required (STREAMLINED)

8329

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority required (STREAMLINED)

8326

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

deferasirox 180 mg tablet, 30

11535D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*1272.18	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 250 mg dispersible tablet, 28

5655P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*1187.34	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

5654N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*593.70	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

5656Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*2374.68	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

11555E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2544.30	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

deferasirox 90 mg tablet, 30

11534C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*636.12	^a CIPLA DEFERASIROX [LR] ^a Deferasirox Sandoz [SZ] ^a Eferas [AF] ^a Pharmacor Deferasirox FC [CR]	^a Deferasirox ARX [XT] ^a DEFERASIROX-TEVA [TB] ^a Jadenu [NM]

■ DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or

- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Authority required

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

deferasirox 250 mg dispersible tablet, 28

11239M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*1187.34	Deferasirox Juno [JU]

deferasirox 125 mg dispersible tablet, 28

11235H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*593.70	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11231D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	2	..	*2374.68	Deferasirox Juno [JU]

▪ DEFERIPRONE

Authority required (STREAMLINED)

6448

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority required (STREAMLINED)

6403

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 1 g tablet, 50

11747G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2311.38	Ferriprox [EU]

deferiprone 100 mg/mL oral liquid, 250 mL

5658T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*963.10	Ferriprox [EU]

deferiprone 500 mg tablet, 100

5657R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*1155.69	Ferriprox [EU]

▪ DESFERRIOXAMINE

Authority required (STREAMLINED)

6394

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

desferrioxamine mesilate 2 g injection, 1 vial

5661Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	60	5	..	*1868.40	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 500 mg injection, 10 vials

5662B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	40	5	..	*5555.20	DBL Desferrioxamine Mesilate [PF]

Drugs for treatment of hyperkalemia and hyperphosphatemia

■ LANTHANUM

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 750 mg chewable tablet, 6 x 15

5781G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*675.94	Fosrenol [TK]

lanthanum 500 mg chewable tablet, 2 x 45

5780F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*447.62	Fosrenol [TK]

lanthanum 1 g chewable tablet, 6 x 15

5782H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*760.96	Fosrenol [TK]

■ SEVELAMER

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9546K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*354.48	^a Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

11855Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*354.48	^a Sevelamer Apotex [TX]	^a Sevelamer Lupin [GQ]

■ SUCROFERRIC OXYHYDROXIDE

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferic oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10233N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*715.78	Velphoro [VL]

Highly Specialised Drugs Program (Community Access)

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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Authority required (STREAMLINED)

7532

Acromegaly

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

7509

Functional carcinoid tumour

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

11315M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2232.74	42.50	Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11289E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*3686.66	42.50	Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

11316N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2955.64	42.50	Somatuline Autogel [IS]

LANREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10075

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.
- WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11736Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*3686.66	42.50	Somatuline Autogel [IS]

■ OCTREOTIDE

Authority required (STREAMLINED)

8197

Acromegaly

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - The condition must be controlled with octreotide immediate release injections, **AND**
 - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
 - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
 - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

8208

Functional carcinoid tumour

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

8198

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11537F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*3527.40	42.50	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11501H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2661.50	42.50	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11512X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*4046.40	42.50	^a Octreotide Depot [TB]	^a Sandostatin LAR [NV]

■ OCTREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10075

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11896D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*4046.40	42.50	^a Octreotide Depot [TB]	^a Sandostatine LAR [NV]

■ ANTIINFECTIVES FOR SYSTEMIC USE

■ ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

■ GANCICLOVIR

Authority required (STREAMLINED)

5000

Cytomegalovirus retinitis

Clinical criteria:

- Patient must be severely immunocompromised, including due to HIV infection.

ganciclovir 500 mg injection, 5 vials

10328N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*249.24	42.50	^a Cymevene [PB]	^a GANCICLOVIR SXP [XC]

■ VALGANCICLOVIR

Authority required (STREAMLINED)

4980

Cytomegalovirus retinitis

Clinical criteria:

- Patient must have HIV infection.

valganciclovir 450 mg tablet, 60

10306K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1143.32	42.50	^a VALGANCICLOVIR HETERO [GG]	^a Valganciclovir Mylan [AF]
						^a Valganciclovir Sandoz [SZ]	

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

10277X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	11	5	..	*#4397.13	42.50	Valcyte [RO]

Protease inhibitors

■ ATAZANAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

atazanavir 200 mg capsule, 60

10349Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*841.00	42.50	Reyataz [BQ]

■ ATAZANAVIR

Note Pharmaceutical benefits that have the form atazanavir 300 mg capsule, 30 and pharmaceutical benefits that have the form atazanavir 300 mg capsule, 60 are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

4512

HIV infection
Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

atazanavir 300 mg capsule, 30

10321F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*632.68	42.50	Reyataz [BQ]

▪ **ATAZANAVIR + COBICISTAT**

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

atazanavir 300 mg + cobicistat 150 mg tablet, 30

10692R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*713.58	42.50	Evotaz [BQ]

▪ **DARUNAVIR**

Note Pharmaceutical benefits that have the form darunavir tablet 600 mg and pharmaceutical benefits that have the form darunavir tablet 600 mg (as ethanolate) are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5094

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 600 mg tablet, 60

10329P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1392.74	42.50	^a Prezista [JC]

darunavir 600 mg tablet, 60

12110J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1392.74	42.50	^a Darunavir Juno [JU]

▪ **DARUNAVIR**

Note Pharmaceutical benefits that have the form darunavir tablet 800 mg and pharmaceutical benefits that have the form darunavir tablet 800 mg (as ethanolate) are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

4313

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
 - The treatment must be in combination with other antiretroviral agents, **AND**
 - The treatment must be co-administered with 100 mg ritonavir, **AND**
 - Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
 - Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.
- Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 800 mg tablet, 30

10367P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*940.28	42.50	^a Prezista [JC]

darunavir 800 mg tablet, 30

12111K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*940.28	42.50	^a Darunavir Juno [JU]

■ FOSAMPRENAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

fosamprenavir 700 mg tablet, 60

10337C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*648.36	42.50	Telzir [VI]

■ RITONAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

ritonavir 100 mg tablet, 30

10273Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*837.94	42.50	Norvir [VE]

■ SAQUINAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

saquinavir 500 mg tablet, 120

10335Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*861.92	42.50	Invirase [RO]

Nucleoside and nucleotide reverse transcriptase inhibitors

▪ **ABACAVIR**

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

abacavir 20 mg/mL oral liquid, 240 mL

10356C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*562.90	42.50	Ziagen [VI]

abacavir 300 mg tablet, 60

10294T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*484.20	42.50	Ziagen [VI]

▪ **ADEFOVIR**

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4490

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Authority required (STREAMLINED)

4510

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

adefovir dipivoxil 10 mg tablet, 30

10290N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*898.52	42.50	APO-Adefovir [TX]

▪ **ENTECAVIR**

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)**5036**

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

entecavir 500 microgram tablet, 30

10279B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*136.28	42.50	^a ENTAC [LR]	^a ENTECAVIR APO [GX]
						^a Entecavir APOTEX [TX]	^a Entecavir GH [GQ]
						^a Entecavir Mylan [AF]	^a ENTECAVIR RBX [RA]
						^a Entecavir Sandoz [SZ]	^a ENTECLUDE [RW]

■ ENTECAVIR

Note PBS-subsidised entecavir monohydrate must be used as monotherapy.

Authority required (STREAMLINED)**5044**

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Authority required (STREAMLINED)**5037**

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

entecavir 1 mg tablet, 30

10353X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*216.74	42.50	^a ENTAC [LR]	^a ENTECAVIR APO [GX]
						^a Entecavir APOTEX [TX]	^a Entecavir GH [GQ]
						^a Entecavir Mylan [AF]	^a ENTECAVIR RBX [RA]
						^a Entecavir Sandoz [SZ]	^a ENTECLUDE [RW]

■ LAMIVUDINE**Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**4454**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**

ANTIINFECTIVES FOR SYSTEMIC USE

- The treatment must be in combination with other antiretroviral agents.

lamivudine 10 mg/mL oral liquid, 240 mL

10320E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*473.54	42.50	3TC [VI]

lamivudine 150 mg tablet, 60

10348P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*144.04	42.50	^a 3TC [VI]	^a Lamivudine Alphapharm [AF]

lamivudine 300 mg tablet, 30

10311Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*144.04	42.50	^a 3TC [VI]	^a Lamivudine Alphapharm [AF]

■ LAMIVUDINE

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

lamivudine 100 mg tablet, 28

10315X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*81.18	42.50	^a Zetlam [AF]
			^B 3.48	*84.66	42.50	^a Zeffix [RW]

■ TENOFOVIR DISOPROXIL

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Note Treatment is intended to prevent mother-to-child transmission of hepatitis B in the third trimester of pregnancy and to reduce the risk of viral reactivation in the mother up to 12 weeks post-partum.

Authority required (STREAMLINED)

10362

Chronic hepatitis B infection

Clinical criteria:

- Patient must be in the third trimester of pregnancy, **AND**
- Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.

tenofovir disoproxil fumarate 300 mg tablet, 30

11992E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*417.54	42.50	^a Tenofovir APOTEX [TX]	^a Tenofovir Sandoz [SZ]
						^a Viread [GI]	

tenofovir disoproxil maleate 300 mg tablet, 30

11982P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*417.54	42.50	^a Tenofovir Disoproxil Mylan [AF]

tenofovir disoproxil phosphate 291 mg tablet, 30

11978K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*417.54	42.50	^a Tenofovir GH [GQ]

■ TENOFOVIR DISOPROXIL

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**6998**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**6982**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**6980**

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)**6992**

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)**6983**

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)**6984**

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

ANTIINFECTIVES FOR SYSTEMIC USE

tenofovir disoproxil fumarate 300 mg tablet, 30

10310P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*417.54	42.50	^a Tenofovir APOTEX [TX] ^a Viread [GI]	^a Tenofovir Sandoz [SZ]

tenofovir disoproxil maleate 300 mg tablet, 30

11155D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*417.54	42.50	^a Tenofovir Disoproxil Mylan [AF]

tenofovir disoproxil phosphate 291 mg tablet, 30

11142K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*417.54	42.50	^a Tenofovir GH [GQ]

■ ZIDOVUDINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

zidovudine 250 mg capsule, 40

10360G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1049.14	42.50	Retrovir [VI]

zidovudine 50 mg/5 mL oral liquid, 200 mL

10361H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	15	5	..	*576.58	42.50	Retrovir [VI]

zidovudine 100 mg capsule, 100

10266H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*702.06	42.50	Retrovir [VI]

Non-nucleoside reverse transcriptase inhibitors

■ EFAVIRENZ

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

efavirenz 600 mg tablet, 30

10366N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*466.60	42.50	Stocrin [MK]

efavirenz 200 mg tablet, 90

10336B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*466.60	42.50	Stocrin [MK]

▪ ETRAVIRINE

Authority required (STREAMLINED)

5014

HIV infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

etravirine 200 mg tablet, 60

10301E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1102.00	42.50	Intelence [JC]

▪ NEVIRAPINE

Authority required (STREAMLINED)

4526

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must have been stabilised on nevirapine immediate release, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

nevirapine 400 mg modified release tablet, 30

10303G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*220.62	42.50	Viramune XR [BY]

▪ NEVIRAPINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

nevirapine 200 mg tablet, 60

10304H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*220.62	42.50	Nevirapine Alphapharm [AF]

nevirapine 10 mg/mL oral liquid, 240 mL

10319D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*1397.78	42.50	Viramune [BY]

▪ RILPIVIRINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

rilpivirine 25 mg tablet, 30

10298B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*544.42	42.50	Edurant [JC]

Integrase inhibitors

■ DOLUTEGRAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

dolutegravir 50 mg tablet, 30

10283F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1312.32	42.50	Tivicay [VI]

■ RALTEGRAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

raltegravir 600 mg tablet, 60

11248B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1185.86	42.50	Isentress HD [MK]

raltegravir 400 mg tablet, 60

10286J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1185.86	42.50	Isentress [MK]

■ RALTEGRAVIR

Authority required (STREAMLINED)

4275

HIV infection

Treatment Phase: Initial

Clinical criteria:

- The treatment must be in combination with other antiretroviral agents, **AND**

- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have a CD4 count of less than 500 per cubic millimetre; OR
- Patient must have symptomatic HIV disease.

Population criteria:

- Patient must be aged 2 years or older.

Authority required (STREAMLINED)

4274

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**
- Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:

- Patient must be aged 2 years or older.

raltegravir 25 mg chewable tablet, 60

10299C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*457.96	42.50	Isentress [MK]

raltegravir 100 mg chewable tablet, 60

10326L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*1779.22	42.50	Isentress [MK]

Antivirals for treatment of HIV infections, combinations

▪ **ABACAVIR + LAMIVUDINE**

Note Pharmaceutical benefits that have the form tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg and pharmaceutical benefits that have the form tablet containing abacavir 600 mg (as hydrochloride) with lamivudine 300 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

4527

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

Authority required (STREAMLINED)

4528

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

abacavir 600 mg + lamivudine 300 mg tablet, 30

10357D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*232.84	42.50	^a ABACAVIR/LAMIVUDINE 600/300 SUN [RA] ^a Kivexa [VI]	^a Abacavir/Lamivudine Mylan [AF]

abacavir 600 mg + lamivudine 300 mg tablet, 30

11246X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*232.84	42.50	^a Abacavir/Lamivudine GH 600/300 [GQ]

▪ **ABACAVIR + LAMIVUDINE + ZIDOVUDINE**

Authority required (STREAMLINED)

4495

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

Authority required (STREAMLINED)

4480

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60

10305J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*507.08	42.50	Trizivir [VI]

NP

▪ **BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMIDE**

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

bictegravir 50 mg + emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30

11649D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1848.46	42.50	Biktarvy [GI]

NP

▪ **DARUNAVIR + COBICISTAT**

Authority required (STREAMLINED)

6413

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority required (STREAMLINED)

6428

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority required (STREAMLINED)

6377

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**

- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

darunavir 800 mg + cobicistat 150 mg tablet, 30

10903W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*953.26	42.50	Prezcobix [JC]

■ DARUNAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR ALAFENAMIDE

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority required (STREAMLINED)

10324

HIV infection

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

Clinical criteria:

- Patient must be antiretroviral treatment naive; OR
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- The treatment must not be in combination with ritonavir.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Authority required (STREAMLINED)

10317

HIV infection

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must not be in combination with ritonavir.

darunavir 800 mg + cobicistat 150 mg + emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30

11955F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1854.96	42.50	Symtuza [JC]

■ DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

Authority required (STREAMLINED)

9981

HIV infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)

10116

HIV infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30

10345L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1442.58	42.50	Triumeq [VI]

■ DOLUTEGRAVIR + LAMIVUDINE

Authority required (STREAMLINED)

9987

HIV infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- Patient must not have suspected resistance to either antiretroviral component.

Authority required (STREAMLINED)**11066**

HIV infection

Treatment Phase: Continuing or change of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

dolutegravir 50 mg + lamivudine 300 mg tablet, 30

11843H

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*1443.34	42.50	Dovato [VI]

NP

■ DOLUTEGRAVIR + RILPIVIRINE**Authority required (STREAMLINED)****8214**

HIV infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority required (STREAMLINED)**8226**

HIV infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

dolutegravir 50 mg + rilpivirine 25 mg tablet, 30

11540J

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*1732.64	42.50	Juluca [VI]

NP

■ EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE**Authority required (STREAMLINED)****4522**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)**4470**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30

11104K

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*1963.90	42.50	Odefsey [GI]

NP

■ EMTRICITABINE + TENOFOVIR ALAFENAMIDE**Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**4454**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30

11099E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1447.90	42.50	Descovy [GI]

emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30

11113X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1447.90	42.50	Descovy [GI]

■ LAMIVUDINE + ZIDOVUDINE**Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**4454**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

lamivudine 150 mg + zidovudine 300 mg tablet, 60

10284G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*217.88	42.50	^a Combivir [VI]	^a Lamivudine 150 mg + Zidovudine 300 mg Alphapharm [AF]

■ LOPINAVIR + RITONAVIR**Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)**4454**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

lopinavir 200 mg + ritonavir 50 mg tablet, 120

10272P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1387.00	42.50	Kaletra [VE]

lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL

10327M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*1309.28	42.50	Kaletra [VE]

lopinavir 100 mg + ritonavir 25 mg tablet, 60

10285H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*355.98	42.50	Kaletra [VE]

■ TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**Authority required (STREAMLINED)****4522**

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)**4470**

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

11114Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1963.90	42.50	Genvoya [GI]

■ TENOFOVIR DISOPROXIL + EMTRICITABINE

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, 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.

Authority required (STREAMLINED)
6985

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)
6986

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

11149T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*119.70	42.50	^a Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF]

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

10347N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*119.70	42.50	^a CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR]	^a Tenofovir/Emtricitabine 300/200 APOTEX [TX]

tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30

12506F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*119.70	42.50	^a Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

11146P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*119.70	42.50	^a Tenofovir EMT GH [GQ]

■ TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ
Authority required (STREAMLINED)
4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)
4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

11732L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*571.22	42.50	Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600 [AF]

Other antivirals

■ MARAVIROC

Authority required (STREAMLINED)

5008

HIV infection

Clinical criteria:

- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

maraviroc 150 mg tablet, 60

10318C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1617.06	42.50	Celsentri [VI]

maraviroc 300 mg tablet, 60

10355B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1617.06	42.50	Celsentri [VI]

■ NERVOUS SYSTEM

■ PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
 - Patient must have completed at least 18 weeks therapy, **AND**
 - Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
 - The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.
- A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

11422E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	148.18	42.50	Versacloz [PF]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Pfizer ClopineCentral.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

NERVOUS SYSTEM

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

10289M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*76.42	42.50	Clopine 25 [PF]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

10302F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*142.24	42.50	Clopine 50 [PF]	

clozapine 50 mg/mL oral liquid, 100 mL

10341G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	148.18	42.50	Clopine Suspension [PF]	

clozapine 100 mg tablet, 100

10358E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.86	42.50	Clopine 100 [PF]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

10288L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*511.94	42.50	Clopine 200 [PF]	

Botulinum Toxin Program

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■ MUSCULO-SKELETAL SYSTEM

■ MUSCLE RELAXANTS

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

Other muscle relaxants, peripherally acting agents

■ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5221

Blepharospasm or hemifacial spasm

Clinical criteria:

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

Population criteria:

- Patient must be aged 12 years or older.

botulinum toxin type A 100 units injection, 1 vial

10997T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

■ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5406

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

botulinum toxin type A 100 units injection, 1 vial

11023E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

■ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5409

Urinary incontinence

Clinical criteria:

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; OR
- Patient must have a spinal cord injury; OR
- Patient must be aged 18 years or older and have spina bifida.

Treatment criteria:

- Must be treated by a urologist; OR

- Must be treated by a urogynaecologist.

botulinum toxin type A 100 units injection, 1 vial

10993N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5359**

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)**8822**

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

botulinum toxin type A 100 units injection, 1 vial

10998W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5178**

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

Authority required (STREAMLINED)**8929**

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR

- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

botulinum toxin type A 100 units injection, 1 vial

10999X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note Special Pricing Arrangements apply.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

11784

Chronic migraine

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

Population criteria:

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

botulinum toxin type A 100 units injection, 1 vial

11000Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6953

Urinary incontinence

Treatment criteria:

- Must be treated by a urologist; OR
- Must be treated by a gynaecologist.

Clinical criteria:

- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

Population criteria:

- Patient must be aged 18 years or older.

botulinum toxin type A 100 units injection, 1 vial

11004E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5408

Severe primary axillary hyperhidrosis

Clinical criteria:

- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

botulinum toxin type A 100 units injection, 1 vial

11016T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.**Note** Special Pricing Arrangements apply.**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.**Authority required (STREAMLINED)****9334**

Moderate to severe spasticity of the lower limb following an acute event

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Clinical criteria:

- The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- Patient must not have established severe contracture in the limb to be treated, **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter.

Population criteria:

- Patient must be aged 18 years or older.

Standard management includes physiotherapy and/or oral spasticity agents.

botulinum toxin type A 100 units injection, 1 vial

11751L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

▪ BOTULINUM TOXIN TYPE A**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.**Note** Special Pricing Arrangements apply.**Authority required (STREAMLINED)****9547**

Moderate to severe spasticity of the upper limb following an acute event

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**

- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

AND

- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

botulinum toxin type A 100 units injection, 1 vial

12017L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1397.74	42.50	Botox [AG]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)
5405

Blepharospasm or hemifacial spasm

Clinical criteria:

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11022D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1095.28	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10987G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1222.34	42.50	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)
5406

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11015R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1095.28	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

11007H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1222.34	42.50	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5178

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

8929

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

12178Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1095.28	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

12214W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1222.34	42.50	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

8822

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11006G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1095.28	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10981Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1222.34	42.50	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**9547**

Moderate to severe spasticity of the upper limb following an acute event

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

AND

- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

10988H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1095.28	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10982B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1222.34	42.50	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**9334**

Moderate to severe spasticity of the lower limb following an acute event

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Clinical criteria:

- The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**

- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- Patient must not have established severe contracture in the limb to be treated, **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter.

Population criteria:

- Patient must be aged 18 years or older.
- Standard management includes physiotherapy and/or oral spasticity agents.

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11857C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1619.02	42.50	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

11831Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1515.98	42.50	Dysport [IS]

■ INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5360**

Blepharospasm

Clinical criteria:

- Patient must have blepharospasm.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

incobotulinumtoxinA 100 units injection, 1 vial

10994P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1472.78	42.50	Xeomin [EJ]

■ INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5222**

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

Population criteria:

- Patient must be aged 18 years or older.

incobotulinumtoxinA 100 units injection, 1 vial

11005F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1472.78	42.50	Xeomin [EJ]

■ INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**9547**

Moderate to severe spasticity of the upper limb following an acute event

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

AND

- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

incobotulinumtoxinA 100 units injection, 1 vial

12087E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1472.78	42.50	Xeomin [EJ]

Growth Hormone Program

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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Somatropin and somatropin agonists

SOMATROPIN

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe growth hormone deficiency

Treatment Phase: Initial treatment of adult onset growth hormone deficiency

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease, **AND**
- Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be in writing and must include:

1. A completed authority prescription form; 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. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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, in a patient with Prader-Willi syndrome and aged 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 adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient aged 18 years or older.

Note 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. EST 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; OR
- Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older.

The authority application must be in writing and must include:

1. A completed authority prescription form; 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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; OR
- Patient must have a diagnosis of Prader-Willi syndrome and be aged 18 years or older.

The authority application must be in writing and must include:

1. A completed authority prescription form; 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. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for 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 10 mg/2 mL injection, 2 mL cartridge

11650E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	426.80	42.50	NutropinAq [IS]

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	..	217.29	42.50	Norditropin FlexPro [NO]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

11495B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	510.59	42.50	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

11493X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	217.29	42.50	Genotropin GoQuick [PF]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of 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), **AND**
- Patient must not have diabetes mellitus, **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 bone age of 2.5 years or less, **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.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation 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 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.

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 diabetes mellitus, **AND**
 - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
 - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
 - Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
 - Patient must be male and must not have a bone age of 15.5 years or more; OR
 - Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **OR**
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. 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.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); **OR**
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; **OR**
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; **OR**
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Confirmation that the patient has precocious puberty; **AND**
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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; OR
- 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
- (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of 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.

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 a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, **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 diabetes mellitus, **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 bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
- (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 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.

somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10514J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Omnitrope Surepal 10 [SZ]

somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

6311E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	SciTropin A [SA]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10518N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Omnitrope Surepal 5 [SZ]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

6476W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Scitropin A [SA]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10446T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Omnitrope Surepal 15 [SZ]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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), **AND**
- Patient must not have diabetes mellitus, **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 bone age of 2.5 years or less, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 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 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
 7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
 8. Confirmation that the patient has hypothalamic obesity; AND
 9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

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 a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, 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 diabetes mellitus, 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 bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 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.

somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge

5822K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Saizen [SG]

somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge

5824M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Saizen [SG]

somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge

3388H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.64	42.50	Saizen [SG]

▪ **SOMATROPIN**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of 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), **AND**
- Patient must not have diabetes mellitus, **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 bone age of 2.5 years or less, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation 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 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **OR**
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); **OR**
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; **OR**
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **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.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 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 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
 7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
 8. Confirmation that the patient has hypothalamic obesity; AND
 9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

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 a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, 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 diabetes mellitus, 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 bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² 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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

5819G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Norditropin FlexPro [NO]

somatropin 10 mg/2 mL injection, 2 mL cartridge

9604L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	426.80	42.50	NutropinAq [IS]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

5818F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	217.29	42.50	Norditropin FlexPro [NO]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

5820H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Norditropin FlexPro [NO]

▪ **SOMATROPIN**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of 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), **AND**
- Patient must not have diabetes mellitus, **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 bone age of 2.5 years or less, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation 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.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have a current height at or below the 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **OR**
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); **OR**
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; **OR**
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **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.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 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 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

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 a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, 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 diabetes mellitus, 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 bone age of 2.5 years or less, AND
- Patient must not have a height greater than or equal to 155.0cm, AND
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **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 prepubertal.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m² ; 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.

somatropin 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6345Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1045.62	42.50	Humatrope [LY]

somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6169Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Humatrope [LY]

somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6170R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Humatrope [LY]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of 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), **AND**
- Patient must not have diabetes mellitus, **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 bone age of 2.5 years or less, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **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.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
 - Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.
- The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
 - (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 6. Confirmation that the patient has precocious puberty; AND
 7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
 8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND
- Patient must have hypothalamic obesity, AND
- Patient must have a growth velocity above the 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 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, AND
- Patient must not have diabetes mellitus, AND
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND
- Patient must not have an active tumour or evidence of tumour growth or activity, AND
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

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 a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, **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 diabetes mellitus, **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 bone age of 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² 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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **AND**

AND

- Patient must not have diabetes mellitus, **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 chronological age of 18 years or greater.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND
5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist
6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

somatropin 400 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10902T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.86	42.50	Genotropin MiniQuick [PF]

somatropin 1 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6314H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	310.48	42.50	Genotropin MiniQuick [PF]

somatropin 1.6 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6317L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	492.11	42.50	Genotropin MiniQuick [PF]

somatropin 800 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6313G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	249.94	42.50	Genotropin MiniQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

9586M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	510.59	42.50	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

9585L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	217.29	42.50	Genotropin GoQuick [PF]

somatropin 1.8 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6318M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	552.65	42.50	Genotropin MiniQuick [PF]

somatropin 1.2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6315J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	371.02	42.50	Genotropin MiniQuick [PF]

somatropin 1.4 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6316K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	431.56	42.50	Genotropin MiniQuick [PF]

somatropin 2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6319N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	613.18	42.50	Genotropin MiniQuick [PF]

somatropin 600 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

9628R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	189.41	42.50	Genotropin MiniQuick [PF]

■ **SOMATROPIN**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of 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'.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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), **AND**
- Patient must not have diabetes mellitus, **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 167.7 cm; OR
- Patient must be female and 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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 commencing treatment

to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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 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.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**

- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of 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.

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 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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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.

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 10 mg/1.5 mL injection, 1.5 mL cartridge

10441M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	SciTropin A [SA]

somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10506Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Omnitrope Surepal 10 [SZ]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10427T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Scitropin A [SA]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10507B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Omnitrope Surepal 5 [SZ]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10490D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Omnitrope Surepal 15 [SZ]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.
The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 commencement 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 commencement 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 commencement 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 commencement 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 commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 commencement 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have been on the maximum dose of 9.5mg/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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 IGF-1 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) 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 (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 clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant 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.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 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 diabetes mellitus, **AND**
 - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
 - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
 - Patient must be male and must not have a bone age of 15.5 years or more; OR
 - Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 10 mg/1.5 mL injection, 1.5 mL cartridge

10451C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Norditropin FlexPro [NO]

somatropin 10 mg/2 mL injection, 2 mL cartridge

10478L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	426.80	42.50	NutropinAq [IS]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10432C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	217.29	42.50	Norditropin FlexPro [NO]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10449Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Norditropin FlexPro [NO]

▪ **SOMATROPIN**

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) 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 (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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).

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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **OR**
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 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.

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 6 mg/1.03 mL injection, 1.03 mL cartridge

10462P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Saizen [SG]

somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge

10483R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Saizen [SG]

somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge

10497L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.64	42.50	Saizen [SG]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 commencement 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 commencement 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 commencement 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 commencement 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 commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

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 commencement 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 commencement 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 IGF-1 levels, **AND**
 - Patient must not have diabetes mellitus, **AND**
 - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
 - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
 - Patient must be male and must not have a bone age of 15.5 years or more; OR
 - Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) 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 (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 clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant 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.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 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 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 diabetes mellitus, **AND**
 - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
 - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
 - Patient must be male and must not have a bone age of 15.5 years or more; OR
 - Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 prepubertal.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 24 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10476J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1045.62	42.50	Humatrope [LY]

somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10482Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Humatrope [LY]

somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10487Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Humatrope [LY]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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**

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

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.

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), **AND**
- Patient must not have diabetes mellitus, **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.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 IGF-1 levels; **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; 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.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; 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.

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 IGF-1 levels; **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
- (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; 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.

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 mosaik 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of 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.

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 diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 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 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.

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 10 mg/1.5 mL injection, 1.5 mL cartridge

10481P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	SciTropin A [SA]

somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10519P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Omnirope Surepal 10 [SZ]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10484T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Scitropin A [SA]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10512G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	224.00	42.50	Omnirope Surepal 5 [SZ]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10485W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Omnirope Surepal 15 [SZ]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 an adverse reaction to growth hormone; OR

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 prepubertal.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

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.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**

8. Recent growth data (height and weight, not older than three months); AND
 9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12

months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 prepubertal.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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 (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 24 mg injection [1 cartridge] (& inert substance diluent [3.15 mL syringe], 1 pack

10502R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1045.62	42.50	Humatrope [LY]

somatropin 6 mg injection [1 cartridge] (& inert substance diluent [3.15 mL syringe], 1 pack

10429X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Humatrope [LY]

somatropin 12 mg injection [1 cartridge] (& inert substance diluent [3.15 mL syringe], 1 pack

10461N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Humatrope [LY]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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**

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

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.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

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 diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 6. Recent growth data (height and weight, not older than three months); AND
 7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**

- Patient must have had a growth velocity above the 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m² ; **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**

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 10 mg/1.5 mL injection, 1.5 mL cartridge

10496K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	440.21	42.50	Norditropin FlexPro [NO]

somatropin 10 mg/2 mL injection, 2 mL cartridge

10438J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	426.80	42.50	NutropinAq [IS]

somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10467X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	217.29	42.50	Norditropin FlexPro [NO]

somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10489C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	656.43	42.50	Norditropin FlexPro [NO]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; **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.

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 IGF-1 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
- (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 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 diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; **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.

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.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

- Patient must be aged 3 years or older.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 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.

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 6 mg/1.03 mL injection, 1.03 mL cartridge

10458K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	267.24	42.50	Saizen [SG]

somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge

10495J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	526.70	42.50	Saizen [SG]

somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge

10442N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	872.64	42.50	Saizen [SG]

■ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of 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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 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 diabetes mellitus, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **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.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; 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.

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.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of

0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR

- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

- Patient must not have a chronological age of equal to or greater than 18 years.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height, weight, and waist circumference, not older than three months); **AND**
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; **AND**
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; **AND**
6. The proprietary name (brand), form and strength of 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.

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
 5. Recent growth data (height and weight, not older than three months); AND
 6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; 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.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m² ; 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 (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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 poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; **AND**
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment or within the last 12 months, and any sleep disorders identified via the polysomnography that required treatment have been addressed; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; **AND**
7. The proprietary name (brand), form and strength of 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.

somatropin 400 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10908D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.86	42.50	Genotropin MiniQuick [PF]

somatropin 1 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10430Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	310.48	42.50	Genotropin MiniQuick [PF]

somatropin 1.6 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10498M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	492.11	42.50	Genotropin MiniQuick [PF]

somatropin 800 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10463Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	249.94	42.50	Genotropin MiniQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

10426R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	510.59	42.50	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

10435F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	217.29	42.50	Genotropin GoQuick [PF]

somatropin 1.8 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10501Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	552.65	42.50	Genotropin MiniQuick [PF]

somatropin 1.2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10457J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	371.02	42.50	Genotropin MiniQuick [PF]

somatropin 1.4 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10434E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	431.56	42.50	Genotropin MiniQuick [PF]

somatropin 2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10472E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	613.18	42.50	Genotropin MiniQuick [PF]

somatropin 600 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10477K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	189.41	42.50	Genotropin MiniQuick [PF]

■ SOMATROPIN**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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; 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.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have been on the maximum dose of 9.5mg/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 diabetes mellitus, **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.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must not have been on the maximum dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist circumference while on the maximum dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

- Patient must not have a chronological age of equal to or greater than 18 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND
6. The proprietary name (brand), form and strength of 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.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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), **AND**
- Patient must not have diabetes mellitus, **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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment; 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; 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.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 IGF-1 levels, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) 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 (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 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 chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 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 non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 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 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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 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 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **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 diabetes mellitus, **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 2.5 years or less, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months; **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.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
 8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 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 (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

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.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/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 diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **AND**
- Patient must not have diabetes mellitus, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND
7. The proprietary name (brand), form and strength of 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.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for 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 400 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10891F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	128.86	42.50	Genotropin MiniQuick [PF]

somatropin 1 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10480N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	310.48	42.50	Genotropin MiniQuick [PF]

somatropin 1.6 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10454F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	492.11	42.50	Genotropin MiniQuick [PF]

somatropin 800 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10479M	1	1	..	249.94	42.50	Genotropin MiniQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10431B	1	1	..	510.59	42.50	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10443P	1	1	..	217.29	42.50	Genotropin GoQuick [PF]

somatropin 1.8 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10500P	1	1	..	552.65	42.50	Genotropin MiniQuick [PF]

somatropin 1.2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10453E	1	1	..	371.02	42.50	Genotropin MiniQuick [PF]

somatropin 1.4 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10488B	1	1	..	431.56	42.50	Genotropin MiniQuick [PF]

somatropin 2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10428W	1	1	..	613.18	42.50	Genotropin MiniQuick [PF]

somatropin 600 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10456H	1	1	..	189.41	42.50	Genotropin MiniQuick [PF]

IVF Treatment Program

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GENITO URINARY SYSTEM AND SEX HORMONES

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

PROGESTOGENS

Pregnen (4) derivatives

PROGESTERONE

Authority required (STREAMLINED)

4997

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 200 mg pessary, 15

9609R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*118.24	42.50	Oripro [ON]

progesterone 100 mg pessary, 15

9608Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*157.18	42.50	Oripro [ON]

progesterone 200 mg pessary, 42

10930G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	87.31	42.50	Utrogestan [HB]

progesterone 100 mg pessary, 21

10116K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*92.02	42.50	Endometrin [FP]

PROGESTERONE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5045

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 8% vaginal gel, 15 applications

6366C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*258.66	42.50	Crinone 8% [SG]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

CHORIOGONADOTROPIN ALFA

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5019

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device

6182J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	58.63	42.50	Ovidrel [SG]

CORIFOLLITROPIN ALFA

Authority required (STREAMLINED)

5009

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for controlled ovarian stimulation, **AND**
- Patient must have an antral follicle count of 20 or less, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, **AND**
- Patient must be undergoing a gonadotrophin releasing antagonist cycle.

corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe

5816D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	413.00	42.50	Elonva [OQ]

corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe

5817E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	673.20	42.50	Elonva [OQ]

■ FOLLITROPIN ALFA
Note Biosimilar prescribing policy

Prescribing of a biosimilar brand, Bemfola or Ovaleap, is encouraged for treatment naive patients.

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 Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

Authority required (STREAMLINED)
5027

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL pen devices

10867Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*2503.87	42.50	Bemfola [FX]

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices

10873G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*859.24	42.50	Bemfola [FX]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL pen device

6432M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*348.36	42.50	^a Gonal-f Pen [SG]

follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge

12770D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1685.18	42.50	^a Ovaleap [TT]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL pen device

6431L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*234.84	42.50	^a Gonal-f Pen [SG]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices

10861P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*433.51	42.50	Bemfola [FX]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL pen device

6433N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1685.18	42.50	^a Gonal-f Pen [SG]

follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge

12800Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*348.36	42.50	^a Ovaleap [TT]

follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge

12779N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*234.84	42.50	^a Ovaleap [TT]

follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL pen devices

10866X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1685.17	42.50	Bemfolia [FX]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices

10872F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1275.82	42.50	Bemfolia [FX]

▪ **FOLLITROPIN ALFA + LUTROPIN ALFA**

Authority required (STREAMLINED)

5250

Stimulation of follicular development

Clinical criteria:

- Patient must have severe LH deficiency, **AND**
- Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device

11667C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1822.90	42.50	Pergoveris [SG]

▪ **FOLLITROPIN BETA**

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

6336L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*996.86	42.50	Puregon 600 IU/0.72 mL [OQ]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

6464F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1815.03	42.50	Puregon 900 IU/1.08 mL [OQ]

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

6335K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*261.20	42.50	Puregon 300 IU/0.36 mL [OQ]

▪ **FOLLITROPIN DELTA**

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin delta 36 microgram/1.08 mL injection, 1.08 mL pen device

11431P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1374.48	42.50	Rekovele [FP]

follitropin delta 12 microgram/0.36 mL injection, 0.36 mL pen device

11430N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*467.73	42.50	Rekovele [FP]

follitropin delta 72 microgram/2.16 mL injection, 2.16 mL pen device

11414R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2170.54	42.50	Rekovele [FP]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

■ HUMAN CHORIONIC GONADOTROPHIN

Authority required (STREAMLINED)

6991

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11154C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	42.52	42.50	Pregnyl [OQ]

human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

11156E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*27.96	29.26	Pregnyl [OQ]

■ HUMAN MENOPAUSAL GONADOTROPHIN

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack

2038G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2066.26	42.50	Menopur 1200 [FP]

human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

2036E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*794.98	42.50	Menopur 600 [FP]

■ LUTROPIN ALFA

Authority required (STREAMLINED)

5251

Stimulation of follicular development

Clinical criteria:

- Patient must have severe LH deficiency, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

lutropin alfa 75 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

10465T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	14	..	..	*1354.58	42.50	Luveris [SG]

■ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

■ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Gonadotropin-releasing hormones

■ NAFARELIN

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

5815C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*221.18	42.50	Synarel [PF]

Anti-gonadotropin-releasing hormones

CETRORELIX

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

cetorelix 250 microgram injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

9599F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*417.58	42.50	Cetrotide [SG]

GANIRELIX

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe

9583J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*349.28	42.50	^a GANIRELIX SUN [RA]	^a Orgalutran [OQ]

ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes

9584K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*349.32	42.50	^a GANIRELIX SUN [RA]	^a Orgalutran [OQ]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ENDOCRINE THERAPY

HORMONES AND RELATED AGENTS

Gonadotropin releasing hormone analogues

TRIPTORELIN

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

triptorelin acetate 100 microgram/mL injection, 7 x 1 mL syringes

10907C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*196.30	42.50	Decapeptyl [FP]

Opiate Dependence Treatment Program

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■ NERVOUS SYSTEM

■ OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in opioid dependence

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Opiate dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.

buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe

11754P	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	369.60	Buvidal Monthly [UR]

buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe

11774Q	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	92.40	Buvidal Weekly [UR]

buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe

11773P	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	92.40	Buvidal Weekly [UR]

buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe

11768J	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	369.60	Buvidal Monthly [UR]

buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe

11767H	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	369.60	Buvidal Monthly [UR]

buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe

11987X	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	±1	369.60	Sublocade [IR]

buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe

11766G	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	92.40	Buvidal Weekly [UR]

buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe

11990C	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	±1	369.60	Sublocade [IR]

buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe

11759X	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	92.40	Buvidal Weekly [UR]

■ BUPRENORPHINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Opiate dependence

Treatment Phase: Maintenance and detoxification (withdrawal)

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

buprenorphine 400 microgram sublingual tablet, 7

6307Y	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	5.85	Subutex [IR]

buprenorphine 2 mg sublingual tablet, 7

6308B	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	9.98	Subutex [IR]

buprenorphine 8 mg sublingual tablet, 7

6309C	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	28.60	Subutex [IR]

▪ **BUPRENORPHINE + NALOXONE**

Note Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Opiate dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28

9749D	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	46.20	Suboxone Film 2/0.5 [IR]

buprenorphine 8 mg + naloxone 2 mg sublingual film, 28

9750E	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer
NP	1	132.44	Suboxone Film 8/2 [IR]

▪ **METHADONE**

Caution The risk of drug dependence is high.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Opiate dependence

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

6171T	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	7.91	^a Aspen Methadone Syrup [AS]	^a Biodone Forte [MW]

methadone hydrochloride 5 mg/mL oral liquid, 1 L

6172W	Max.Qty Packs	Price ex manufacturer \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	33.20	^a Aspen Methadone Syrup [AS]	^a Biodone Forte [MW]

Extemporaneously Prepared Benefits

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia, powdered	BP	0.03	0.31	2.82	17.90
Acetic Acid (33 per cent)	BP	0.02	0.17	1.68	16.79
Acetic Acid (6 per cent)	BP	0.01	0.04	0.40	4.01
Acetone (use as additive only)	BP	0.02	0.17	1.50	13.34
Alum	BP	0.02	0.20	1.78	15.84
Aluminium Acetate Solution	BP	0.02	0.20	1.83	16.31
Anise Water Concentrated 1 in 40	BP	0.01	0.08	0.77	7.66
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.07	0.59	5.21
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.05	0.49	4.38	27.83
Aspirin	BP	0.10	1.00	8.96	79.63
Belladonna Tincture	BP	0.03	0.33	2.97	26.42
Benzocaine	BP	0.19	1.86	10.60	106.00
Benzoic Acid	BP	0.19	1.93	17.36	110.20
Benzoic Acid Compound Ointment	APF	0.02	0.21	1.89	16.79
Benzoic Acid Solution	BP	0.02	0.21	2.11	21.06
Benzoin Compound Tincture	BP	0.04	0.44	3.93	34.91
Boric Acid (use as additive only)	BP	0.06	0.58	5.22	33.15
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.18	1.65	10.46
Calcium Hydroxide	BP	0.12	1.16	10.44	66.30
Calcium Hydroxide Solution	BP	0.01	0.02	0.23	2.32
Castor Oil (use as additive only)	BP	0.01	0.12	1.05	9.37
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.51	4.55
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.17	1.37	12.21
Chlorhexidine Acetate (use as additive only)	BP	10.94	109.39	625.10	6251.00
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.05	0.48	4.31
Chloroform (use as additive only)	BP	0.10	0.95	8.59	76.38
Chloroform Spirit	BP	0.01	0.09	0.86	8.64
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.11	1.14	11.38
Citric Acid Monohydrate	BP	0.10	0.95	8.55	54.30
Coal Tar	BP	0.06	0.63	5.68	50.47
Coal Tar Solution	BP	0.03	0.26	2.38	15.10
Cocaine Hydrochloride	BP	7.38	73.75	421.43	4214.32
Coconut Oil	BP	0.05	0.50	4.52	28.68
Codeine Linctus	APF	0.02	0.16	1.41	8.94
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	7.56	75.58	431.90	4319.00
Collodion Flexible	BP	0.46	4.63	41.65	264.43
Dithranol	BP	3.78	37.76	215.78	2157.82
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.15	1.35	11.98
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	2.60	26.04	234.39	1488.20
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.05	0.46	4.07
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.06	0.56	5.00
Ether Solvent (use as additive only)	BP	0.29	2.35	18.83	167.36
Eucalyptus Oil (use as additive only)	BP	0.02	0.22	1.95	17.34
Ferrous Sulfate	BP	0.04	0.36	3.28	20.85
Formaldehyde Solution	BP	0.03	0.30	2.67	23.77

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.01	0.12	1.07	9.52
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.09	0.68	5.42	48.17
Iodine	BP	0.37	3.67	20.97	209.67
Iodine Alcoholic Solution	BP	0.04	0.43	3.91	24.85
Iodine Aqueous Oral Solution	BP	0.04	0.38	3.46	22.00
Kaolin Mixture	BPC 1968	0.02	0.18	1.58	14.04
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.08	0.76	6.81	43.25
Lavender Spike Oil	BPC 1968	0.13	1.04	8.32	73.91
Liquorice Liquid Extract	BP	0.17	1.67	15.02	133.53
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.05	0.47	4.13
Magnesium Trisilicate	BP	0.05	0.53	4.74	42.17
Menthol, Racemic or Levomenthol	BP	0.37	3.71	33.43	212.24
Methyl Hydroxybenzoate	BP	0.43	4.29	38.62	245.20
Methyl Hydroxybenzoate Solution	APF	0.04	0.44	4.37	43.70
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.09	0.79
Olive Oil (use as additive only)	BP	0.01	0.10	0.88	7.82
Paraffin Hard	BP	0.06	0.64	5.80	51.56
Paraffin Light Liquid	BP	0.03	0.33	2.94	18.68
Paraffin Liquid (use as additive only)	BP	0.01	0.09	0.82	7.28
Paraffin Soft White	BP	0.01	0.08	0.68	6.01
Peppermint Oil (use as additive only)	BP	0.10	0.96	8.68	55.12
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.05	0.46	4.10	36.47
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	1.26	12.59	113.34	719.60
Phenol Liquefied (not available for ear drops)	BP	0.44	4.41	39.65	251.72
Podophyllum Resin	BP	4.19	41.92	239.54	2395.40
Potassium Citrate	BP	0.03	0.30	2.67	23.71
Potassium Iodide	BP	0.50	4.99	44.87	284.90
Potassium Permanganate	BP	0.04	0.40	3.58	31.83
Propyl Hydroxybenzoate	BP	0.39	3.94	35.47	225.20
Propylene Glycol	BP	0.03	0.26	2.34	14.87
Resorcinol	BP	0.45	3.57	28.59	254.15
Salicylic Acid	BP	0.04	0.43	3.86	24.51
Salicylic Acid Ointment	APF	0.02	0.17	1.38	12.23
Salicylic Acid Ointment	BP	0.02	0.17	1.38	12.23
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.03	0.27	2.43	21.57
Sodium Chloride	BP	0.03	0.26	2.35	20.93
Sodium Chloride Solution	BP	0.01	0.15	1.33	8.46
Sodium Citrate	BP	0.03	0.34	3.07	19.52
Sodium Thiosulfate (use as additive only)	BP	0.05	0.48	4.35	38.66
Starch	BP	0.02	0.16	1.44	12.81
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.01	0.14	1.45	14.46
Sulfur Precipitated	BP 1980	0.03	0.30	2.69	17.09
Syrup	BP	0.01	0.06	0.57	5.03
Talc Purified, sterilised	BP	4.97	49.74	447.67	3979.31
Thymol	BP	0.51	5.13	46.18	293.20
Thymol Compound Mouth Wash	APF 15	0.01	0.14	1.26	11.24
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.10	1.00	10.01
Tragacanth Mucilage	BPC 1973	0.01	0.09	0.93	9.32
Tragacanth, powdered	BP	0.64	6.38	57.44	364.70
Trichloroacetic Acid	BP 1980	0.42	4.24	38.13	242.12
Triethanolamine	BP	0.14	1.40	12.62	80.13

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0.00	0.00	7.40	7.40
Water Purified	BP	0.01	0.01	0.13	1.17
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.03	0.21	1.64	14.55
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.03	0.28	2.48	22.05
Wool Fat Hydrous	BP	0.03	0.32	2.92	25.93
Zinc Compound Paste	BP	0.04	0.37	3.36	29.86
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.02	0.25	2.22	19.69
Zinc Oxide	BP	0.04	0.38	3.41	30.29
Zinc Sulfate	BP	0.08	0.79	7.08	44.95
Zinc and Salicylic Acid Paste	BP	0.04	0.37	3.36	29.86

Container Prices

Type	Container	Price \$
Dispensing Bottles	25mL	1.74
Dispensing Bottles	50mL	0.64
Dispensing Bottles	100mL	0.97
Dispensing Bottles	200mL	1.36
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	0.95
Poison Bottles	50mL	0.82
Poison Bottles	100mL	0.93
Poison Bottles	200mL	1.16
Poison Bottles	500mL	2.00
Dropper Containers (Glass)	15mL	1.24
Dropper Containers (Polythene)	15mL	0.98
Screw Cap Jars	25g	1.20
Screw Cap Jars	50g	1.51
Screw Cap Jars	100g	1.37
Screw Cap Jars	200g	0.77
Screw Cap Jars	500g	2.19

Standard Formula Preparations

Code	Item	Reference	DPMQ \$	MRVSN \$
	Creams			
7502W	(Maximum Quantity 100 g and 1 Repeat) Salicylic Acid and Sulfur Aqueous	APF	17.65	19.32
	Ear Drops			
	(Maximum Quantity 15 ml and 2 Repeats)			
7643G	Aluminium Acetate	BP	13.55	15.22
7642F	Aluminium Acetate	APF	12.54	14.21
7314Y	Sodium Bicarbonate	APF & BP	11.67	13.34
7313X	Spirit	APF	11.32	12.99
	Inhalations			
	(Maximum Quantity 50 ml and 1 Repeat)			
7484X	Benzoin and Menthol	APF	33.60	35.27
7308P	Menthol	APF	16.59	18.26
7310R	Menthol and Eucalyptus	BP1980	17.65	19.32
	Linctuses containing Codeine Phosphate			
	(Maximum Quantity 100 ml and 0 Repeat)			
7530H	Codeine	APF	19.69	21.36
	Lotions			
	(Maximum Quantity 200 ml and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	15.04	16.71
	Mixtures, Other			
	(Maximum Quantity 200 ml and 4 Repeats)			
7348R	Kaolin	BPC 1968	31.03	32.70
7342K	Magnesium Trisilicate	BPC 1968	26.67	28.34
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	28.15	29.82
	Ointments, Waxes			
	(Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF & BP	27.97	29.64
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	21.65	23.32
7926E	Salicylic Acid	APF	23.87	25.54
7928G	Salicylic Acid (extemporaneous formula)	BP	23.87	25.54
	Paints			
	(Maximum Quantity 25 ml and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	176.32	42.50
7568H	Salicylic Acid	APF	105.55	42.50
	Pastes, Other			
	(Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF & BP	41.05	42.50
	Powders for Internal Use			
	(Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	53.36	42.50

Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

Index of Manufacturers' Code

Code	Manufacturer	Code	Manufacturer
AB	Abbott Australasia Pty Ltd	GX	Apotex Pty Ltd
AE	AFT Pharmaceuticals (AU) Pty Ltd	GZ	sanofi-aventis Australia Pty Ltd
AF	Alphapharm Pty Ltd	HB	Besins Healthcare Australia Pty Ltd
AG	Allergan Australia Pty Limited	HQ	Generic Health Pty Ltd
AL	Alphapharm Pty Ltd	HR	Paul Hartmann Pty Ltd
AN	Amgen Australia Pty Limited	HT	BTC Speciality Health Pty Ltd
AP	AstraZeneca Pty Ltd	HX	Sandoz Pty Ltd
AQ	Alcon Laboratories (Australia) Pty Ltd	IB	Apotex Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited	IG	Sigma Company Limited
AV	sanofi-aventis Australia Pty Ltd	IJ	I-Care Pharma Distributors Pty Ltd
BB	Blackmores Limited	IL	iNova Pharmaceuticals (Australia) Pty Limited
BD	Biogen Australia Pty Ltd	IM	iNova Pharmaceuticals (Australia) Pty Limited
BE	Beiersdorf Australia Ltd	IO	BioMarin Pharmaceutical Australia Pty Ltd
BG	Sandoz Pty Ltd	IQ	Alcon Laboratories (Australia) Pty Ltd
BN	Bayer Australia Ltd	IR	Indivior Pty Ltd
BQ	Bristol-Myers Squibb Australia Pty Ltd	IS	Ipsen Pty Ltd
BR	B. Braun Australia Pty Ltd	IT	InterPharma Pty Ltd
BV	BSN medical (Aust.) Pty Ltd	IX	Clinect Pty Ltd
BX	Baxter Healthcare Pty Limited	IY	Clinect Pty Ltd
BY	Boehringer Ingelheim Pty Ltd	JB	Apotex Pty Ltd
BZ	Boucher & Muir Pty Ltd	JC	Janssen-Cilag Pty Ltd
CC	ConvaTec Australia Pty Ltd	JJ	Johnson & Johnson Medical Pty Ltd
CF	CNS Pharma Pty Ltd	JO	Juno Pharmaceuticals Pty Ltd
CH	Apotex Pty Ltd	JT	Johnson & Johnson Pacific Pty Limited
CJ	Celgene Pty Limited	JU	Juno Pharmaceuticals Pty Ltd
CR	Pharmacor Pty Limited	JX	Juno Pharmaceuticals Pty Ltd
CS	Seqirus (Australia) Pty Ltd	KE	Kendall Australasia Pty Ltd
CT	Coloplast Pty Ltd	KI	KCI Medical Australia Pty Ltd
CU	Care Pharmaceuticals Pty Limited	KP	Eli Lilly Australia Pty Ltd
CX	Contact Lens Centre Australia Limited	KY	Key Pharmaceuticals Pty Ltd
DE	Stallergenes Australia Pty Ltd	LC	Lohmann & Rauscher Pty Ltd
DJ	De Fries Industries Pty Ltd	LI	Luminarie Pty Ltd
DQ	Church & Dwight (Australia) Pty Ltd	LL	Astellas Pharma Australia Pty Ltd
DV	Medical Developments International Limited	LM	Link Medical Products Pty Ltd
DX	Ascensia Diabetes Care Australia Pty Limited	LN	Aspen Pharmacare Australia Pty Limited
DZ	Medsurge Healthcare Pty Ltd	LO	Leo Pharma Pty Ltd
EA	Amneal Pharmaceuticals Pty Ltd	LQ	Astellas Pharma Australia Pty Ltd
ED	Amneal Pharmaceuticals Pty Ltd	LR	Cipla Australia Pty Ltd
EF	Amneal Pharmaceuticals Pty Ltd	LS	Astellas Pharma Australia Pty Ltd
EI	Eisai Australia Pty Ltd	LT	Aspen Pharmacare Australia Pty Limited
EJ	Encapsulate Pharma Pty Ltd	LU	Lundbeck Australia Pty Ltd
EO	Ego Pharmaceuticals Pty Ltd	LV	Luminarie Pty Ltd
EU	Chiesi Australia Pty Ltd	LX	Lawley Pharmaceuticals Pty Ltd
EV	Teva Pharma Australia Pty Ltd	LY	Eli Lilly Australia Pty Ltd
EW	Celltrion Healthcare Australia Pty Ltd	MF	Mundipharma Pty Limited
FB	Pierre Fabre Australia Pty Ltd	MH	Molnlycke Health Care Pty Ltd
FD	Dr Falk Pharma Australia Pty Ltd	MK	Merck Sharp & Dohme (Australia) Pty Ltd
FF	Phebra Pty Ltd	MM	3M Pharmaceuticals Australia Pty Ltd
FG	Phebra Pty Ltd	MQ	Alphapharm Pty Ltd
FI	Boehringer Ingelheim Pty Ltd	MT	Mentholatum Australasia Pty Ltd
FJ	Pharmaco (Australia) Limited	MW	Biomed Aust Pty Limited
FK	A.Menarini Australia Pty Limited	NE	Norgine Pty. Ltd.
FO	For Benefit Medicines Pty Ltd	NF	Novo Nordisk Pharmaceuticals Pty. Limited
FP	Ferring Pharmaceuticals Pty Limited	NI	Novo Nordisk Pharmaceuticals Pty. Limited
FQ	Pharmaco (Australia) Limited	NM	Novartis Pharmaceuticals Australia Pty Limited
FX	Gedeon Richter Australia Pty Ltd	NO	Novo Nordisk Pharmaceuticals Pty. Limited
FZ	Pfizer Australia Pty Ltd	NQ	Takeda Pharmaceuticals Australia Pty. Ltd.
GA	Galderma Australia Pty Ltd	NT	Nestle Australia Ltd
GC	GlaxoSmithKline Australia Pty Ltd	NU	Nutricia Australia Pty Limited
GG	Gem Pharma Pty Ltd	NV	Novartis Pharmaceuticals Australia Pty Limited
GH	Amdipharm Mercury (Australia) Pty Limited	OB	Oral B Laboratories Pty Ltd
GI	Gilead Sciences Pty Limited	OC	Accord Healthcare Pty. Ltd.
GJ	GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	OD	Accord Healthcare Pty. Ltd.
GK	GlaxoSmithKline Australia Pty Ltd	OE	Omegapharm Pty Ltd
GN	Actavis Pty Ltd	OH	Orpharma Pty Ltd
GO	Mylan Health Pty Ltd	OM	Colgate Oral Care
GQ	Generic Health Pty Ltd	ON	Orion Laboratories Pty. Ltd.
GT	Mylan Health Pty Ltd	OQ	Organon Pharma Pty Ltd
		OS	Otsuka Australia Pharmaceutical Pty. Ltd

Code	Manufacturer
OU	Oraderm Pharmaceuticals Pty Ltd
OV	Organon Pharma Pty Ltd
OW	Arrow Pharma Pty Ltd
PB	Pharmaco (Australia) Limited
PE	Allergan Australia Pty Limited
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
PP	Petrus Pharmaceuticals Pty Ltd
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd
QH	Cortex Health Pty Ltd
QS	Sandoz Pty Ltd
RA	Sun Pharma ANZ Pty Ltd
RB	Bio Revive Pty Ltd
RC	Reckitt Benckiser (Australia) Pty Limited
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RJ	Recordati Rare Diseases Australia Pty. Ltd.
RM	Pharmacor Pty Limited
RN	Sun Pharma ANZ Pty Ltd
RO	Roche Products Pty Ltd
RW	Arrow Pharma Pty Ltd
RX	Servier Laboratories (Aust.) Pty. Ltd.
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SA	SciGen (Australia) Pty Limited
SB	Nutricia Australia Pty Limited
SE	Servier Laboratories (Aust.) Pty. Ltd.
SG	Merck Healthcare Pty Ltd
SI	Sigma Company Limited
SN	Smith & Nephew Pty Limited
SS	SSL Australia Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SY	Bayer Australia Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Ltd
TD	STADA Pharmaceuticals Australia Pty Limited
TF	Te Arai BioFarma Limited
TI	Teva Pharma Australia Pty Ltd
TK	Takeda Pharmaceuticals Australia Pty. Ltd.
TM	Technipro PulmoMed Pty Ltd
TQ	Terumo BCT Australia Pty Limited
TS	Specialised Therapeutics Australia Pty Ltd
TT	Theramex Australia Pty Ltd
TW	Apotex Pty Ltd
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
UC	UCB Australia Proprietary Limited
UJ	Upjohn Australia Pty Ltd
UL	Bausch & Lomb (Australia) Pty Ltd
UM	Unomedical Pty Ltd
UN	Unilever Australia Limited
UO	Bausch & Lomb (Australia) Pty Ltd
UR	Camurus Pty Ltd
VE	AbbVie Pty Ltd
VF	Vitaflo Australia Pty Limited
VI	ViiV Healthcare Pty Ltd
VL	Vifor Pharma Pty Limited
VO	Avallon Pharmaceuticals Pty Limited
VR	Vertex Pharmaceuticals (Australia) Pty. Ltd.
VZ	Sanofi-aventis Healthcare Pty Ltd
WA	sanofi-aventis Australia Pty Ltd
WC	Wockhardt Bio Pty Ltd
XC	Southern Cross Pharma Pty Ltd
XH	MS Health Pty Ltd
XI	Alexion Pharmaceuticals Australasia Pty Ltd
XN	Southern XP Pty Ltd
XT	Arrotex Pharmaceuticals Pty Ltd
YC	Cipla Australia Pty Ltd
YN	Mayne Pharma International Pty Ltd
YT	Mayne Products Pty Ltd

Code	Manufacturer
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ZO	Swedish Orphan Biovitrum Pty Ltd
ZP	Medis Pharma Pty Ltd
ZS	Strides Pharma Science Pty Ltd

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